FEDERAL SECURITY AGENCY

FOOD AND DRUG ADMINISTRATION

NOTICES OF JUDGMENT UNDER THE FEDERAL FOOD, DRUG, AND COSMETIC ACT

[Given pursuant to section 705 of the Food, Drug, and Cosmetic Act]

2301–2350

DRUGS AND DEVICES

The cases reported herewith were instituted in the United States district courts by the United States attorneys acting upon reports submitted by direction of the Federal Security Administrator.

OSCAR R. EWING, *Administrator, Federal Security Agency.*

WASHINGTON, D. C., *September 10, 1948.*

CONTENTS*

DRUGS ACTIONABLE BECAUSE OF POTENTIAL DANGER WHEN USED ACCORDING TO DIRECTIONS

2301. Adulteration and misbranding of Anademin Tablets. U. S. v. Anademin Chemical Co. Plea of guilty. Fine, $200. (F. D. C. No. 21457. Sample No. 14079–H.)

INFORMATION FILED: May 5, 1947, Eastern District of Tennessee, against the Anademin Chemical Co., a corporation, Chattanooga, Tenn.

ALLEGED SHIPMENT: On or about April 8, 1946, from the State of Tennessee into the State of Ohio.

LABEL, IN PART: "Tablets Anademin Strophanthus 1/1500 grain (containing 1/15000 grain of Strophanthin), Squill 4¾ grains, Canadian Hemp (Apocynum) 1/64 grain and Elder Flowers (Sambucus) 1/32 grain * * * Assay: As assayed by the method described in U. S. P. XII for Digitalis, each tablet has a potency of 1.25 U. S. P. Digitalis units."

NATURE OF CHARGE: Adulteration, Section 501 (c), the strength of the article differed from that which it purported and was represented to possess, in that each tablet was represented to possess a potency, as assayed by the method described in the United States Pharmacopoeia XII for digitalis, of not more

*For presence of a habit-forming narcotic without warning statement, see No. 2309; omission of, or unsatisfactory, ingredients statements, Nos. 2306, 2307, 2331, 2333, 2342; imitation of, and sale under name of, another drug, No. 2312; failure to bear a label containing an accurate statement of the quantity of the contents, Nos. 2306, 2307, 2330, 2342; failure to bear a label containing the name and place of business of the manufacturer, packer, or distributor, No. 2330; cosmetics, subject to the drug provisions of the Act, Nos. 2331, 2337.

807126—49——1

than 1.25 U. S. P. digitalis units, whereas each tablet when so assayed was found to possess a potency of more than 1.25 U. S. P. digitalis units.

Misbranding, Section 502 (a), the label statement "As assayed by the method described in U. S. P. XII for Digitalis, each tablet has a potency of 1.25 U. S. P. Digitalis units" was false and misleading; and, Section 502 (j), the article was dangerous to health when used in the dosage and with the frequency and duration suggested in the labeling, i. e., "As assayed by the method described in U. S. P. XII for Digitalis, each tablet has a potency of 1.25 U. S. P. Digitalis units * * * Caution: To be used only by or on the prescription of a physician." The quoted labeling suggested administration of the article in dosages appropriate for administration of tablets having a potency of 1.25 U. S. P. digitalis units, whereas if the drug were prescribed by a physician in reliance upon such statement of potency, the patient would receive approximately 2½ times the intended dosage of a potent drug.

DISPOSITION: November 5, 1947. A plea of guilty having been entered, the court imposed a fine of $100 on each of the two counts of the information.

2302. Misbranding of Thytocin with Pilocarpine. U. S. v. George A. Breon & Co., Inc. Plea of nolo contendere. Fine, $300 and costs. (F. D. C. No. 23262, Sample Nos. 50403–H, 55226–H, 83028–H.)

INFORMATION FILED: May 28, 1948, Western District of Missouri, against George A. Breon & Co., Inc., Kansas City, Mo.

ALLEGED SHIPMENT: On or about August 12, September 7, and October 23, 1946, from the State of Missouri into the States of Louisiana, Georgia, and Tennessee.

NATURE OF CHARGE: Misbranding, Section 502 (a), the label statements "Each tablet contains: * * * Pilocarpine hydrochloride . . . 1/30 gr." was false and misleading, since each tablet of the article contained more than 1/30 grain of pilocarpine hydrochloride, i. e., in a portion of the article, approximately 0.429 grain and, in the remainder, 0.406 grain.

Further misbranding, Section 502 (j), the article was dangerous to health when used in the dosage and with the frequency and duration suggested in the labeling "Each tablet contains: * * * Pilocarpine hydrochloride . . . 1/30 gr. * * * Caution: To be dispensed only by or on the prescription of a physician." The labeling suggested administration of the article in dosages appropriate for administration of tablets having a potency of 1/30 grain of pilocarpine hydrochloride, whereas the article if administered in dosages appropriate for the administration of tablets having such potency, would be dangerous to health, since if prescribed by a physician in reliance upon such statement of potency, the patient would receive approximately 12 or 13 times the intended dosage of a potent drug.

DISPOSITION: June 23, 1948. A plea of nolo contendere having been entered, the court imposed a fine of $300 and costs.

2303. Adulteration and misbranding of Firmo cream. U. S. v. 12 Dozen Jars, etc. (F. D. C. No. 23401. Sample No. 90367–H.)

LIBEL FILED: August 6, 1947, District of Columbia.

PRODUCT: 12 dozen 2-ounce jars and 30 dozen 4-ounce jars of *Firmo cream*, together with a number of circulars. The product and circulars were in interstate commerce in the District of Columbia, in the possession of, and held for sale by, Maynard H. Smith, Washington, D. C. Examination showed that the product contained estradiol.

LABEL, IN PART: "Firmo Contains 7500 I. U. of Natural Estrogenic Hormones Per Oz. of Cream Directions Each night thoroughly cleanse the skin, then gently massage a generous amount of the cream into the tissue * * * Continental Sales Co. Wash., D. C."

NATURE OF CHARGE: Adulteration, Section 501 (d), an article containing estradiol had been substituted for an article containing natural estrogenic hormones.

Misbranding, Section 502 (a), the statements in the labeling which represented and suggested that the article was an aphrodisiac, were false and misleading, since the article was not an aphrodisiac; Section 502 (f) (1), the labeling of the article failed to bear adequate directions for use; and, Sec-

tion 502 (j), the article was dangerous to health when used in the dosage or with the frequency or duration prescribed, recommended, or suggested in the labeling.

DISPOSITION: April 9, 1948. Default decree of condemnation and destruction.

DRUG REQUIRING CERTIFICATE OR RELEASE, FOR WHICH NONE HAD BEEN ISSUED

2304. Misbranding of penicillin sodium. U. S. v. 998 Cartons * * *. (F. D. C. No. 23192. Sample No. 64200–H.)

LIBEL FILED: June 18, 1947, Southern District of New York.

ALLEGED SHIPMENT: On or about March 28, 1947, by Barich, Inc., from Rutherford, N. J.

PRODUCT: 998 cartons, each containing 5 vials, of *penicillin sodium* at New York, N. Y.

LABEL, IN PART: (Cartons) "5 vials 100,000 Units Each Penicillin Sodium (Crystalline) * * * Eto Pharmacal Company, New York 17, New York."

NATURE OF CHARGE: Misbranding, Section 502 (a), the labeling of the article was misleading, since it failed to reveal the fact that Eto Pharmacal Company was not the manufacturer of the article, which fact was material in the light of the unmodified words "Eto Pharmacal Company" appearing on the label; and the label statement "Lot No. B 5 * * * Nov. 1, 49" was misleading, in that it represented and suggested that the article had been certified under such identifying mark in accordance with regulations promulgated by the Federal Security Administrator, whereas such was not the case.

Further misbranding, Section 502 (f) (1), the labeling of the article failed to bear adequate directions for use; and, Section 502 (l), the article was represented as a drug composed wholly of penicillin sodium, a derivative of a kind of penicillin, and it was not from a batch with respect to which a certificate or release had been issued pursuant to law.

DISPOSITION: December 17, 1947. Ekstrand & Tholand, Inc., claimant, having admitted the allegations of the libel, judgment of condemnation was entered and the product was ordered released under bond to be brought into compliance with the law, under the supervision of the Food and Drug Administration.

2305. Misbranding of penicillin sodium. U. S. v. 36 Cartons, etc. (F. D. C. No. 23178. Sample Nos. 54399–H, 54400–H.)

LIBEL FILED: June 6, 1947, Middle District of North Carolina.

ALLEGED SHIPMENT: On or about May 15, 1947, by the Institutional Products Co., from New York, N. Y.

PRODUCT: 36 cartons, each containing 5 500,000-unit vials, and 87 cartons, each containing 5 200,000-unit vials, of penicillin sodium at Winston-Salem, N. C.

LABEL, IN PART: "Penicillin Sodium Proctor * * * Proctor Laboratories 475 Fifth Avenue, New York * * * Lot No. 90 [or "Lot No. 77"]."

NATURE OF CHARGE: Misbranding, Section 502 (a), the labeling was misleading, since it failed to reveal the fact that Proctor Laboratories was not the manufacturer of the article, which fact was material in the light of the unmodified words "Proctor Laboratories" appearing thereon; and the label statements "Lot No. 90," appearing on the 36-carton lot, and "Lot No. 77, appearing on the 87-carton lot, were misleading, since they represented and suggested that the article had been certified under such identifying marks in accordance with the regulations, when such was not the case.

Further misbranding, Section 502 (f) (1), the labeling of the article failed to bear adequate directions for use; and, Section 502 (l), the article was represented as a drug composed wholly of penicillin sodium, a derivative of a kind of penicillin, and it was not from a batch with respect to which a certificate or release had been issued pursuant to the provisions of the Act.

DISPOSITION: March 24, 1948. Default decree of condemnation. The product was ordered delivered to a Federal institution.

DRUGS ACTIONABLE BECAUSE OF FAILURE TO BEAR ADEQUATE DIRECTIONS OR WARNING STATEMENTS*

2306. Action to enjoin and restrain the interstate shipment of "Nature's Vegetation." U. S. v. Edgar H. Gremore. Injunction granted. (Inj. No. 82.)

COMPLAINT FILED: On or about March 3, 1945, Eastern District of Wisconsin, against Edgar H. Gremore, Florence, Wis.

NATURE OF CHARGE: That the defendant was engaged in the manufacture, processing, and packing of a product known as "Nature's Vegetation"; that the product consisted essentially of a moist, earthy material containing nitrogenous and carbonaceous material and mineral residues; that the defendant prepared the product from peat from a peat bog on his farm near Florence, Wis.; that for several years he had been packaging and selling the material in interstate commerce; that he had made many consignments of the product in the years 1944 and 1945; that he had sent to certain of these consignees certain circulars separate from the shipments of the product; that the label and circulars represented that the product would cure, prevent, and constitute an adequate treatment for human diseases, such as cancer, heart disease, arthritis, neuritis, eczema, tumors, abscesses, varicose veins, and other human ailments; and that the drug "Nature's Vegetation" had absolutely no therapeutic value in the treatment or prevention of any of the said human diseases. The complaint alleged further that the drug was misbranded as follows:

Section 502 (a), the label of the product bore false and misleading representations;

Section 502 (b) (2), the label failed to bear an accurate statement of the quantity of the contents;

Section 502 (e), the label failed to bear the common or usual name of the article; and,

Section 502 (f) (1), the label failed to bear adequate directions for use.

PRAYER OF COMPLAINT: That the defendant be restrained and enjoined during the pendency of the action and after trial permanently enjoined from shipping misbranded drugs in interstate commerce.

DISPOSITION: On March 19, 1945, the court entered a temporary injunction against the defendant. On June 11, 1945, the defendant having failed to answer or otherwise plead to the complaint, the court handed down its findings of fact and conclusions of law, sustaining the allegations in the complaint; and, in accordance therewith, judgment was entered permanently enjoining the defendant from introducing or delivering for introduction into interstate commerce any product or products which were misbranded within the meaning of Sections 502 (a) and 502 (e) of the Act.

2307. Adulteration and misbranding of Holliday's Antiseptic Powder and misbranding of Holliday's Solution #5, Holliday's Cinotol-F, Holliday's Vaginal Ointment, and Holliday's Para Specific. U. S. v. Austin J. Holliday (Holliday's Pharmacal Laboratory). Plea of not guilty. Tried to the court. Verdict of guilty. Imposition of sentence suspended and defendant placed on probation for 5 years. (F. D. C. No. 23249. Sample Nos. 49581–H to 49585–H, incl.)

INFORMATION FILED: December 22, 1947, Eastern District of Texas, against Austin J. Holliday, trading as Holliday's Pharmacal Laboratory, Beaumont, Tex.

ALLEGED SHIPMENT: On or about August 21, 1946, from the State of Texas into the State of Louisiana.

PRODUCT: Analyses disclosed that *Holliday's Solution #5* was essentially a sweetened and colored solution of epsom salt; that *Holliday's Cinotol-F* consisted essentially of ferrous iron, potassium bromide, and potassium iodide in solution; that *Holliday's Vaginal Ointment* was a salve having a petrolatum base and containing methyl salicylate and sulfapyridine; that *Holliday's Antiseptic Powder* consisted of salt artificially colored, perfumed with oil of wintergreen, and containing traces of sulfate, aluminum, and some cresolic substance; and that *Holliday's Para Specific* was essentially a solution of potassium bromide, iodide, iron and ammonium citrate, and a small amount of arsenic.

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*See also Nos. 2303–2305.

LABEL, IN PART: "Holliday's Solution #5 [or "Cinotol-F," "Vaginal Ointment," "Para Antiseptic Powder," or "Para Specific"] * * * Holliday's Pharmacal Laboratories Los Angeles, Calif."

NATURE OF CHARGE: *Holliday's Solution #5.* Misbranding, Section 502 (a), the label statement "Alkalinity Hydro-Laxative" was false and misleading, since it represented and suggested that the article possessed alkalizing properties, whereas it did not possess such properties; and, Section 502 (b) (2), the label of the article bore no statement of the quantity of the contents.

Holliday's Cinotol-F. Misbranding, Section 502 (a), the label statement "Women" was misleading, since it represented and suggested that the article would be of value in the treatment of female diseases, whereas the article would not be of such value; Section 502 (e) (2), the article was not designated solely by a name recognized in an official compendium and was fabricated from two or more ingredients, and its label failed to bear the common or usual name of each active ingredient, including the name, quantity, or proportion of potassium bromide, since the label failed to bear a statement of any of the ingredients of the article; Section 502 (f) (2), the article contained potassium bromide, and its labeling failed to bear a warning that a drug containing potassium bromide should not be used by persons with kidney disease, a warning that frequent and continued use of a drug containing potassium bromide may lead to mental derangement, skin eruptions, or other serious defects, and a warning against taking more than the dosage recommended; and, Section 502 (b) (2), the label of the article bore no statement of the quantity of the contents.

Holliday's Vaginal Ointment. Misbranding, Section 502 (a), the label statement "Vaginal" was misleading, since it represented and suggested that the article would be of value in the treatment of conditions affecting women, whereas it would not be of such value; and, Section 502 (e) (2), the article was not designated solely by a name recognized in an official compendium and was fabricated from two or more ingredients, and its label failed to bear the common or usual name of each active ingredient, since its label failed to bear a statement of any of its ingredients.

Holliday's Antiseptic Powder. Adulteration, Section 501 (c), the strength of the article differed from, and its quality fell below, that which it was represented to possess, in that it was represented to be an antiseptic, whereas it was not an antiseptic within the meaning of the law, since it was not a germicide and did not purport to be and was not represented as an antiseptic for inhibitory use as a wet dressing, ointment, dusting powder, or such other use as involves prolonged contact with the body. Misbranding, Section 502 (a), the label statement "Antiseptic Powder" was false and misleading, since the article was not an antiseptic within the meaning of the law; and, Section 502 (b) (2), the label of the article bore no statement of the quantity of the contents.

Holliday's Para Specific. Misbranding, Section 502 (a), the label statement "Specific Blood, Lues, Vitality" was false and misleading, since it represented and suggested that the article would be efficacious in the treatment of syphilis and would furnish vitality to the user, whereas it would not be efficacious in the treatment of syphilis and would not furnish vitality to the user. Further misbranding, Section 502 (b) (2), the label of the article bore no statement of the quantity of the contents; Section 502 (e) (2), the article was not designated solely by a name recognized in an official compendium and was fabricated from two or more ingredients, and its label failed to bear the common or usual name of each active ingredient, including the name, quantity, and proportion of potassium bromide and arsenic, since its label failed to bear a statement of any of the ingredients of the article; and, Section 502 (f) (2), the article contained potassium bromide, and its labeling failed to bear a warning that a drug containing potassium bromide should not be used by a person with kidney disease, a warning that frequent and continued use of such drug may lead to mental derangement, skin eruptions, or other serious defects, and a warning against taking more than the dosage recommended.

DISPOSITION: A plea of not guilty having been entered, the case came on for trial before the court on March 16, 1948. The trial was concluded on the same day, with the return of a verdict of guilty, whereupon the court suspended imposition of sentence and placed the defendant on probation for 5 years.

2308. Misbranding of Schoell's 202 Treatment. U. S. v. Arthur Schoell (Schoell Manufacturing Co.). Plea of nolo contendere. Fine, $250. (F. D. C. No. 23229. Sample No. 19590–H.)

INFORMATION FILED: October 2, 1947, Northern District of California, against Arthur Schoell, trading as the Schoell Manufacturing Co., Los Gatos, Calif.

ALLEGED SHIPMENT: On or about August 13, 1946, from the State of California into the State of Minnesota.

PRODUCT: Examination showed that the treatment consisted of 20 capsules, each of which contained aloin, manganese dioxide, oil of cassia, apiol green, and capsicum; and of two suppositories which contained potassium alum, tannin, sodium chloride, sodium borate, and magnesium sulfate.

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements on the label, and in a leaflet entitled "Schoell's 202 Treatment" which was enclosed with the article, were false and misleading. These statements represented and suggested that the article would be efficacious in the treatment of unnatural irregularities due to colds and other minor causes, and that it would be efficacious in the treatment of painful, irregular, and unnatural delayed menstruations. The article would not be efficacious for the purposes so represented.

Further misbranding, Section 502 (f) (2), the labeling of the article failed to bear adequate warnings against use in those pathological conditions where its use may be dangerous to health, since the capsules were a laxative and the labeling failed to bear a warning that they should not be used when abdominal pain, nausea, vomiting, or other symptoms of appendicitis were present.

DISPOSITION: October 31, 1947. A plea of nolo contendere having been entered, the court imposed a fine of $250.

2309. Misbranding of ephedrine and amytal pulvules. U. S. v. Cohen Drug Co., Inc., and Saul Cohen. Pleas of nolo contendere. Fine, $1,800 against corporation. Indictment dismissed with respect to individual. (F. D. C. No. 21474. Sample Nos. 42232–H, 42233–H, 42235–H, 42237–H, 42240–H, 42242–H, 42618–H to 42620–H, incl.)

INDICTMENT RETURNED: April 9, 1947, Southern District of West Virginia, against the Cohen Drug Company, Inc., Charleston, W. Va., and Saul Cohen.

ALLEGED SHIPMENT: Between the approximate dates of March 15 and May 21, 1946, from the State of Ohio into the State of West Virginia.

LABEL, WHEN SHIPPED: "Pulvules No. 44 Ephedrine and Amytal * * * Warning—May be Habit Forming. Caution—To be used only by or on the prescription of a physician * * * Eli Lilly and Company Indianapolis, U. S. A."

ALLEGED VIOLATION: On or about July 2, 9, 16, and 17, 1946, and while the drug was being held for sale after shipment in interstate commerce, the defendant caused a number of the said "Pulvules" (capsules) to be removed from the bottles bearing the labels described above, to be repackaged into boxes and labeled "Ephedrine and Amytal," and to be sold without a prescription.

NATURE OF CHARGE: That the defendant caused the drug to be misbranded, as follows: Section 502 (d), the product was a drug for use by man and contained a chemical derivative of barbituric acid, which derivative has been designated by the regulations as habit forming, and its label failed to bear a statement containing the name and quantity or proportion of the chemical derivative of barbituric acid and, in juxtaposition therewith, the statement, "Warning—May be habit forming"; Section 502 (f) (1), the labeling failed to bear adequate directions for use; and, Section 502 (f) (2), it failed to bear adequate warnings against use in those pathological conditions, and by children, where its use may be dangerous to health, and against unsafe dosage and methods and duration of administration.

DISPOSITION: May 5, 1947. A plea of nolo contendere having been entered, the court imposed a fine of $200 on each of the 9 counts against the corporation and ordered the action against the individual dismissed.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF DEVIATION FROM OFFICIAL OR OWN STANDARDS*

2310. Adulteration and alleged misbranding of drug tablets. U. S. v. Charles H. Dietz, Inc. Motion to dismiss overruled. Plea of guilty to counts charging adulteration; fine, $350. Counts charging misbranding dismissed. (F. D. C. No. 20116. Sample Nos. 10249–H, 10484–H, 13723–H, 16765–H, 18526–H, 18554–H, 20078–H.)

INFORMATION FILED: July 22, 1946, Eastern District of Missouri, against Charles H. Dietz, Inc., St. Louis, Mo.

ALLEGED SHIPMENT: Between the approximate dates of January 12, 1944, to March 17, 1945, from the State of Missouri into the States of Pennsylvania, Ohio, Illinois, Minnesota, Nebraska, and Arkansas.

LABEL, IN PART: "Special Chocolate Coated Tablets R/3081 * * * Manufactured for McAdams Bros. Pittsburgh, Pa.," "Tablet Sugar Coated Red Strychnine Sulphate * * * Charles H. Dietz, Inc.," "Special Compressed Tablets Rx 2743 Pink * * * Manufactured for Jones Surg. Sup. Co., Cleveland, Ohio," "C. T. Acetanilide Comp. R/3099 * * * Manufactured for I. H. Scheef & Co. La Grange, Ill.," "Special Enteric Red Tablet Rx/2528 * * * Manufactured for Physicians and Hospitals Supply Co., Minneapolis, Minn.," "Special SC Red Tablet Rx 2752 * * * Manufactured for McDonald Pharm. Co. St. Paul, Minn.," or "Enteric SC Red Tablet R/2940 * * * Manufactured for Master Labs., Inc. Omaha, Nebr."

NATURE OF CHARGE: Adulteration, Section 501 (b), the *strychnine sulfate tablets* purported to be and were represented as a drug, the name of which, "Strychnine Sulphate Tablets," is recognized in the United States Pharmacopoeia, an official compendium, and their strength differed from the standard set forth therein, since they were represented as containing in each tablet 1/60th of a grain of strychnine sulfate, as determined by the methods of assay set forth in the compendium, whereas the article contained a lesser amount of strychnine sulfate. Further adulteration, Section 501 (c), the strength of the other tablets involved differed from that which they purported and were represented to possess. The representations made on the labels of these tablets were as follows: That the *Special Chocolate-Coated Tablets R/3081* contained 2 grains of sodium bicarbonate; that the *Special Compressed Tablets Rx 2743* contained ½ grain of caffeine alkaloid; that the *C. T. Acetanilide Comp. Tablets R/3099* contained 1 grain of acetanilide, ½ grain of caffeine alkaloid, 1 grain of sodium bromide, 1 grain of sodium salicylate, and 1 grain of sodium bicarbonate; that the *Special Enteric Red Tablet Rx/2528* contained 1 grain of sodium nitrite; that the *Special SC Red Tablet Rx 2752* contained 1/50 grain of arsenious acid and 1/60 grain of strychnine sulfate; and that the *Enteric SC Red Tablet R/2940* contained 1.932 grains of nicotine sulfate. The tablets contained less than the declared amounts of these ingredients.

Misbranding, Section 502 (a), the labels of the tablets, which represented that the tablets contained the amount of the ingredients indicated above, were charged to be false and misleading because of deficiency in the amount of these ingredients in the tablets.

DISPOSITION: On September 30, 1946, a motion to dismiss was filed on behalf of the defendant, and on November 21, 1946, suggestions in support thereof were filed, arguing in substance that each count failed to charge an offense, because the amount of shortage was not alleged in each instance. It was argued further that counts 2, 4, 6, 8, 10, 12, and 14 were duplicitous in that they charged misbranding of the respective products charged to be adulterated in counts 1, 3, 5, 7, 9, 11, and 13, and that such alleged adulteration and misbranding constitutes but one offense in the case of each product. In addition, a motion for a bill of particulars was subsequently filed for the defendant. On December 6, 1946, the court overruled the defendant's motion to dismiss and sustained the motion for a bill of particulars to the extent of requiring that the Government state the date of the Government's analysis of each tablet involved and the result obtained by such analysis. A bill of particulars was accordingly filed on December 13, 1946. Thereafter, on motion of the Government, the counts

*See also Nos. 2303, 2307.

of the information covering the misbranding charges were dismissed. A plea of guilty was entered to the remaining counts, and on May 29, 1947, the court imposed a fine of $50 on each of the 7 counts.

2311. Adulteration and misbranding of Diet Tablets. U. S. v. National Drug Laboratories, Inc., and Jules Press. Pleas of guilty. Fines, $2,000 and costs against corporation and $250 and costs against individual. (F. D. C. No. 23219. Sample No. 65559–H.)

INFORMATION FILED: October 6, 1947, Northern District of Illinois, against the National Drug Laboratories, Inc., Chicago, Ill., and Jules Press, president of the corporation.

ALLEGED SHIPMENT: On or about April 29, 1946, from the State of Illinois into the State of Pennsylvania.

LABEL, IN PART: "Diet Tablets * * * Distributed by Vitamix Corporation Philadelphia, Pa."

NATURE OF CHARGE: Adulteration, Section 501 (c), the strength of the article differed from that which it was represented to possess, in that each tablet was represented to contain 1/360 grain of atropine sulfate, whereas each tablet contained more than 1/360 grain of atropine sulfate.

Misbranding, Section 502 (a), the label statement "Atropine Sulphate 1/360 grain" was false and misleading.

The information alleged also that certain other products were adulterated and misbranded under the provisions of the law applicable to foods, as reported in notices of judgment on foods.

DISPOSITION: January 29, 1948. Pleas of guilty having been entered, the court imposed fines of $2,000 and costs against the corporation and $250 and costs against the individual.

2312. Adulteration and misbranding of thyroid powder. U. S. v. 1 Drum * * * (and 1 other seizure action). (F. D. C. Nos. 24326, 24327. Sample Nos. 13039–K, 13040–K.)

LIBELS FILED: On or about February 2 and 10, 1948, District of New Jersey and Eastern District of Pennsylvania.

ALLEGED SHIPMENT: On or about November 17 and 20, 1947, by the National Drug Laboratories, Inc., from Chicago, Ill.

PRODUCT: 1 300-pound drum and 1 100-pound drum of *thyroid powder* at Wenonah, N. J., and Philadelphia, Pa., respectively.

NATURE OF CHARGE: Adulteration, Section 501 (b), the article purported to be and was represented as a drug, thyroid, the name of which is recognized in the United States Pharmacopoeia, an official compendium, and its strength differed from, and its purity fell below, the official standard, since it contained less than 0.17 percent of iodine in thyroid combination and was not free from iodine in inorganic combination; and, Section 501 (d), a substance, iodine in a combination other than that peculiar to the thyroid gland, had been mixed and packed with the article so as to reduce its quality and strength, and had been substituted in part therefor.

Misbranding, Section 502 (i) (2), the article was an imitation of another drug, thyroid; and, Section 502 (i) (3), it was offered for sale under the name of another drug, thyroid.

DISPOSITION: March 5 and April 5, 1948. Default decrees of condemnation and destruction.

2313. Adulteration of elixir of phenobarbital. U. S. v. Herman Achs (Certified Laboratories). Plea of guilty. Defendant fined $100 and sentenced to 6 months in jail. Jail sentence suspended. (F. D. C. No. 23236. Sample No. 65188–H.)

INFORMATION FILED: September 18, 1947, Eastern District of Pennsylvania, against Herman Achs, trading as Certified Laboratories, Philadelphia, Pa.

ALLEGED SHIPMENT: On or about October 3, 1946, from the State of Pennsylvania into the State of New Jersey.

NATURE OF CHARGE: Adulteration, Section 501 (d) (2), a substance consisting essentially of an aqueous alcoholic solution containing phenobarbital, glycerin, saccharin, and cudbear, together with an aromatic material resembling orange oil, had been substituted for "Elixir of Phenobarbital," a drug the name of

which is recognized in the United States Pharmacopoeia, and which in accordance with the specifications of the Pharmacopoeia does not contain tincture of cudbear and saccharin.

DISPOSITION: November 26, 1947. A plea of guilty having been entered, the court imposed a fine of $100 and sentenced the defendant to 6 months in jail, which sentence was suspended.

2314. Adulteration of calcium levulinate and obstetrical pituitary. U. S. v. American Bio-Chemical Corporation, Al G. Johns, and Joseph A. Blakeslee. Pleas of nolo contendere. Fine of $500 against corporation and $300 against each individual. (F. D. C. No. 22015. Sample Nos. 30695–H, 48267–H, 48289–H.)

INFORMATION FILED: August 1, 1947, Southern District of California, against the American Bio-Chemical Corp., Los Angeles, Calif., and Al G. Johns, president and treasurer, and Joseph A. Blakeslee, vice-president and secretary, of the corporation. The defendants were charged with the interstate shipment, on or about September 19, 1946, of a quantity of *obstetrical pituitary* and with giving a false guaranty with respect to the *calcium levulinate*. The guaranty was given on or about December 5, 1945, to Nathan Melnick, doing business as the Vitamin-Endocrine Co., Los Angeles, Calif. It provided that the article comprising each shipment or delivery made by the defendant to the latter firm would be neither adulterated nor misbranded within the meaning of the Federal Food, Drug, and Cosmetic Act. On or about June 20, 1946, the defendants delivered to the Vitamin-Endocrine Co. a quantity of *calcium levulinate*, which was shipped on or about June 26, 1946, by that company in the name of the Jerry Lindeman Co., from the State of California into the State of Arizona.

NATURE OF CHARGE: *Calcium levulinate*. Adulteration, Section 501 (c), the purity and quality of the article fell below that which it purported and was represented to possess. The article was represented to be a sterile solution suitable for intravenous administration, whereas it was not a sterile solution but was contaminated with viable molds and yeasts, and it was not suitable for intravenous administration, in that it was contaminated with viable molds and yeasts and undissolved material.

Obstetrical pituitary. Adulteration, Section 501 (b), the article purported to be and was represented as a drug, the names of which, i. e., "Posterior Pituitary Injection" and "Solution of Pituitary," are recognized in the United States Pharmacopoeia, an official compendium, and its strength differed from the official standard. The potency of the article was such that 0.1 cc. possessed an activity equivalent to less than 1 U. S. P. Posterior Pituitary Unit, whereas the official compendium provides that "The potency of Posterior Pituitary Injection shall be such that 0.1 cc. of the Injection shall possess an activity equivalent to one U. S. P. Posterior Pituitary Unit"; and its difference in strength from the standard was not plainly stated, or stated at all, on its label.

The information alleged also the interstate shipment of another product, Tri-B-Lex Vitamin B Complex, which was adulterated under the provisions of the law applicable to foods, as reported in notices of judgment on foods.

DISPOSITION: August 11, 1947. Pleas of nolo contendere having been entered, the court imposed fines of $500 against the corporation and $300 against each individual.

2315. Adulteration of sodium iodide. U. S. v. 850 Ampuls * * *. (F. D. C. No. 23518. Sample No. 66692–H.)

LIBEL FILED: July 22, 1947, Eastern District of Pennsylvania.

ALLEGED SHIPMENT: On or about May 15, 1947, by the Estro Chemical Co., Inc., from New York, N. Y.

PRODUCT: 850 10 cc.-size ampuls of *sodium iodide* at Philadelphia, Pa.

NATURE OF CHARGE: Adulteration, Section 501 (b), the article purported to be and was represented as a drug, "Ampuls of Sodium Iodide," the name of which is recognized in the National Formulary, an official compendium, and its quality and purity fell below the standard set forth therein, since the compendium provides that ampul solutions must be substantially free of any undissolved material, and the article was contaminated with undissolved material.

DISPOSITION: February 2, 1948. Default decree of condemnation and destruction.

2316. Adulteration and misbranding of cod liver oil and misbranding of Nelson's Solid Liniment. U. S. v. Arthur A. Kain and Philip Stern. Pleas of guilty. Fines, $200 against each individual, plus costs. (F. D. C. No. 21487. Sample Nos. 40330–H, 42616–H.)

INFORMATION FILED: July 31, 1947, Northern District of Ohio, against Arthur A. Kain, vice-president, and Philip Stern, secretary-treasurer, of the Cleveland Druggists' Specialties Co., Cleveland, Ohio.

ALLEGED SHIPMENT: On or about February 25 and March 26, 1946, from the State of Ohio into the States of Missouri and West Virginia.

PRODUCT: Analysis disclosed that the *cod liver oil* was a white viscous emulsion containing a small amount of calcium and sodium, with no appreciable amount of vitamin B_1, and less than 12,500 U. S. P. units of vitamin A and less than 1,275 U. S. P. units of vitamin D per fluid ounce; and that the *Nelson's Solid Liniment* was a red-colored ointment of aromatic odor and irritating properties, containing chiefly mustard and mixed aromatics.

LABEL, IN PART: "Nor-Cod-Mul White Emulsion of Cod Liver Oil with Creosote * * * Great Lakes Laboratories Cleveland Ohio," or "Nelson's Solid Liniment * * * Great Lakes Laboratories Cleveland, Ohio."

NATURE OF CHARGE: *Cod liver oil.* Adulteration, Section 501 (c), the strength of the article fell below that which it purported and was represented to possess, since each fluid ounce of the article was represented to contain 25,000 U. S. P. units of vitamin A, 2,200 International Units of vitamin B_1, and 2,550 U. S. P. units of vitamin D, whereas the article contained less than those amounts of vitamin A, vitamin B_1, and vitamin D. Misbranding, Section 502 (a), the label statements "Contains Per Fluid Ounce: Vitamin A 25,000 U. S. P. Units vitamin B_1 2,200 International Units vitamin D 2,550 U. S. P. Units" were false and misleading. Further misbranding, Section 502 (a), certain label statements represented and suggested that the article possessed rejuvenating qualities for undernourished children; that it would be of value for run-down adults and children; that it would be efficacious in the cure, mitigation, treatment, and prevention of coughs, colds, and bronchitis; and that it would assist nature to build up body resistance. These statements were false and misleading, since the article did not possess rejuvenating qualities for undernourished children and would not be efficacious for the purposes represented.

Nelson's Solid Liniment. Misbranding, Section 502 (a), certain label statements were false and misleading, since they represented and suggested that the article would be efficacious in the treatment of all external pains, rheumatism, backache, and sprains. The article would not be efficacious in the treatment of those conditions.

DISPOSITION: December 17, 1947. Pleas of guilty having been entered, the court imposed a fine of $200 and costs against each defendant.

2317. Adulteration and misbranding of powdered belladonna leaves. U. S. v. 1 Drum * * *. (F. D. C. No. 24420. Sample No. 27210–K.)

LIBEL FILED: On or about January 21, 1948, Eastern District of Missouri.

ALLEGED SHIPMENT: On or about June 28, 1946, by Allaire, Woodward & Co., from Peoria, Ill.

PRODUCT: 1 drum, containing 20 pounds, of *powdered belladonna leaves* at St. Louis, Mo.

LABEL, IN PART: "Powdered Belladonna Leaf Atropa Belladonna U. S. P."

NATURE OF CHARGE: Adulteration, Section 501 (d), a mixture of stramonium leaves and belladonna leaves had been substituted in whole or in part for belladonna leaves, which the article was represented to be.

Misbranding, Section 502 (a), the label statement "Powdered Belladonna Leaf Atropa Belladonna U. S. P." was false and misleading as applied to the article, which consisted of a mixture of powdered belladonna leaf and stramonium leaf and which did not meet the specifications of the United States Pharmacopoeia for belladonna leaf.

DISPOSITION: March 8, 1948. Default decree of condemnation and destruction.

2318. Adulteration of cascara sagrada. U. S. v. 300 Bags * * *. (F. D. C. No. 23058. Sample No. 70014–H.)

LIBEL FILED: June 23, 1947, Northern District of Illinois.

ALLEGED SHIPMENT: On or about February 8, 1947, by R. J. Prentiss & Co., Inc., from New York, N. Y.

PRODUCT: 300 bags, containing a total of 10,078 pounds, of *cascara sagrada* at Freeport, Ill.

NATURE OF CHARGE: Adulteration, Section 501 (b), the article purported to be and was represented as a drug, the name of which is recognized in the United States Pharmacopoeia, and its quality and purity fell below the official standard, since the Pharmacopoeia provides that vegetable drugs are to be as free as practicable from molds and shall show no abnormal discoloration, whereas the article was contaminated with mold and was discolored.

DISPOSITION: August 5, 1947. W. T. Rawleigh Co., Freeport, Ill., claimant, having consented to the entry of a decree, judgment of condemnation was entered and the product was ordered released under bond for segregation and destruction of the unfit portion, under the supervision of the Federal Security Agency. The segregation operations resulted in the destruction of 25 bags of the product as unfit.

2319. Adulteration and misbranding of antiseptic mouth wash and misbranding of witch hazel. U. S. v. James J. Kaplan (Diamond Drug and Magnesia Co.). Plea of guilty. Fine, $100. (F. D. C. No. 21472. Sample Nos. 12714–H, 12734–H, 56689–H, 56845–H.)

INFORMATION FILED: August 22, 1947, District of Massachusetts, against James J. Kaplan, trading as the Diamond Drug & Magnesia Co., at Boston, Mass.

ALLEGED SHIPMENT: On or about October 18, 1945, and January 7 and February 2 and 7, 1946, from the State of Massachusetts into the States of New Hampshire, Rhode Island, and Maine.

LABEL, IN PART: "Berkeley Brand Antiseptic Mouth Wash * * * Distributed by Berkeley Drug & Chemical Co., Boston, Mass.," "Peerless Antiseptic Mouth Wash * * * Distributed by Peerless Products Co., Boston Mass.," "Eluto's Witch Hazel * * * Distributed by Eluto Bros., Inc., Manchester, N. H.," or "Nyler Quality Products Witch Hazel * * * Eastern Distributor The Jayson Co., Portland, Maine."

NATURE OF CHARGE: *Antiseptic mouth wash.* Adulteration, Section 501 (c), the strength of the article differed from, and its quality fell below, that which it was represented to possess, in that it was represented to be an antiseptic when diluted to one-half strength, whereas when diluted to one-half strength it was not an antiseptic within the meaning of Section 201 (o), since it was not a germicide when so diluted and did not purport to be and was not represented as an antiseptic for inhibitory use as a wet dressing ointment, dusting powder, or such other use as involved prolonged contact with the body. Misbranding, Section 502 (a), the label statement "Antiseptic * * * Use ½ * * * strength" was false and misleading.

Witch hazel. Misbranding, Section 502 (a), the label statements "For the relief of Sprains, Bruises * * * Burns, Scalds * * * Chilblains" were false and misleading, since they represented and suggested that the article would be an effective treatment for sprains, burns, bruises, scalds, and chilblains, whereas it would not be an effective treatment for such conditions.

DISPOSITION: March 2, 1948. A plea of guilty having been entered, the court imposed a fine of $100.

2320. Adulteration and misbranding of prophylactics. U. S. v. Crown Rubber Sundries Co. and Joseph Lader. Pleas of not guilty. Tried to the court. Verdict of guilty. Fine, $800 and costs. (F. D. C. No. 15578. Sample Nos. 105–H, 2589–H, 13537–H, 22909–H.)

INFORMATION FILED: August 23, 1945, Northern District of Ohio, against the Crown Rubber Sundries Co., a partnership, Akron, Ohio, and Joseph Lader, a partner.

ALLEGED SHIPMENT: On or about January 18 and February 15 and 28, 1945, from the State of Ohio into the States of Florida, West Virginia, Indiana, and Missouri.

LABEL, IN PART: (Boxes) "Red-Pak * * * Packed by W. H. Reed & Co. Atlanta, Ga. [or "Packed by Crown Rubber Co. Akron, Ohio"]," "Red-Pack * * * Manufactured by Killian Mfg. Co. Akron, Ohio," or "Seal-Tex * * * Seal Rubber Co. Akron, Ohio"; (portions of devices) "Genuine Liq-

uid Latex Mfd. by L. E. Shunk Latex Prod. Inc., Akron, Ohio," or "Mfd. By Shunk Latex Prod. Inc. Akron, Ohio."

NATURE OF CHARGE: Adulteration, Section 501 (c), the quality of the article fell below that which it purported and was represented to possess. The article purported to be and was represented as a prophylactic, but would be ineffective for prophylactic purposes because of the presence of holes and perforations.

Misbranding, Section 502 (a), the following statements appearing in the labeling of the various shipments were false and misleading: "Prophylactic," "For prevention of disease," "Prophylactics * * * guaranteed for five years," "For prevention of disease only," "The Pink of Perfection * * * Prophylactics * * * Made From the Highest Quality of Pure Rubber * * *," and "Guaranteed to Conform to All Regulations * * * The within articles are manufactured to be sold and used for the prevention of disease."

DISPOSITION: May 27, 1946. Pleas of not guilty having been entered, the matter was tried before the court. The defendants were found guilty and were fined $2,400, together with costs. On July 12, 1946, the court handed down the following memorandum opinion:

FREED, *District Judge:* "The matter for decision involves the interpretation of Title 21 U. S. C. A. § 333 (c).

"What is the extent of the immunity granted by this section to a distributor, who has branded and sold a product relying upon a guaranty of compliance with the Federal Food, Drug and Cosmetic Act, received from his manufacturer or seller in good faith?

"The essential facts are not in dispute.

"Crown Rubber Sundries Co., a partnership; and one of the partners, individually, Joseph Lader, were charged in eight counts of an information alleging violation of Title 21 U. S. C. A. 331 (a) and Title 21 U. S. C. A. 352 (a) in the shipment and sale of rubber prophylactics which were, in fact, ineffective for prophylactic purposes because of the presence of holes and perforations in the devices.

"It is not disputed that the goods shipped in interstate commerce were adulterated and misbranded.

"The defendants rely solely upon the claim that they are free from guilt because they received a guaranty given them by the L. E. Shunk Latex Products Inc., the manufacturer, warranting that all the merchandise complied with the provisions of the Pure Food, Drug and Cosmetic Act, and authorizing them to make the same guaranty to their distributees.

"The undisputed facts show that the defendants received the merchandise in bulk, that they repacked the prophylactics in individual containers bearing their own labels and shipped them to their own customers. There was some evidence tending to show that the merchandise was acquired by the purchase of a wholesale business which had in stock the prophylactics which the original owner had purchased from the Shunk Company.

"Since the purchase was not made directly from the manufacturer, it is questioned whether the guaranty made to these defendants could inure to their benefit. It is urged by the Government that the guaranty which affords a defense is only one which is made to him who purchases directly from the guarantor.

"Although the court is of the opinion that the Government's contention in this regard is correct, the real issue is whether the defense of the guaranty, as a matter of law, can be made under the state of the evidence which is not in dispute.

"Assuming, for the purpose of the instant case, that the defendants did have a right to rely upon a guaranty received from someone other than the person from whom they purchased the merchandise, the question remains whether the guaranty affords a defense under the statute.

"The decided cases have not dealt with the question here raised. The report of the Congressional committees throws no light upon the intent of Congress as affects the immediate issue.

"The effect of the guaranty, in the Committees' report, is touched upon briefly as affording protection to a manufacturer who ships his products to distant processors who, in turn, package and label the finished merchandise. The committees' report indicates it was the intent of Congress to relieve the

manufacturer of the effect of violations of the Act that result from the processing of his products by others for whom the manufacturer should not be liable.

"Neither the reported cases, nor the Committees' report deals with the question of the defense available to the shipper who holds a guaranty from the manufacturer.

"It is fundamental that the purpose of the Act is to protect the consumer. Public policy casts upon those who introduce foods, drugs and cosmetics into interstate commerce the duty of rigid inspection. They are charged with absolute responsibility for proper branding of their products. Public safety demands of them not only extreme care, but definite assurance of the quality of their products.

"It is the judgment of this court that no person may rely upon any guaranty unless, in introducing the product into interstate commerce, he has acted merely as a conduit through which the merchandise reaches the consumer.

"The protection of the exemption clause of the statute does not include within its ambit those who, in any way handle or process the product to which the guaranty attaches, if one has been given.

"The guaranty can be received in good faith, within the meaning of the statute, only if the shipper passes the product on in the same form as he receives it, without repacking it or subjecting it to any new hazards of adulteration or failure which were not present when the original guaranty upon which he relies was given.

"The facts in this case show the prophylactics were purchased by the defendants in bulk and that they repackaged and relabeled them. They shipped them in cartons bearing their own trade name.

"When this state of facts appears, in the judgment of the court, as a matter of law, the defense of the guaranty no longer is available to the defendants.

"Such an interpretation, the court believes, would be in accord with the intent of Congress, as reflected both by the general purpose of the Act and the language of the Committees in treating the extent of the defense available to the manufacturer.

"Since the defense of the guaranty is not available to the defendants, and since the evidence establishes every other element of the offenses charged, it is the judgment of the court that they must be found guilty of the violations charged in the information."

On February 11, 1947, the defendants having petitioned for a mitigation of the sentence, the court reduced the fine from $2,400 to $800.

2321. Adulteration and misbranding of prophylactics. U. S. v. Allied Latex Corporation. Plea of guilty. Fine, $5,400. (F. D. C. No. 5579. Sample Nos. 5557–E, 5558–E, 19662–E, 27493–E, 27494–E, 36368–E, 39501–E, 39985–E, 42958–E, 48610–E, 48611–E, 48613–E, 48615–E, 48616–E, 48618–E to 48621–E, incl., 50139–E, 51583–E, 51587–E, 51993–E, 51994–E, 54206–E, 54207–E, 62569–E, 74123–E, 74781–E.)

INFORMATION FILED: February 26, 1942, District of New Jersey, against the Allied Latex Corporation, East Newark, N. J.

ALLEGED SHIPMENT: Between the approximate dates of October 12, 1940, and September 23, 1941, from the State of New Jersey into the States of Georgia, Maryland, Massachusetts, Missouri, New York, Ohio, Pennsylvania, and Rhode Island.

LABEL, IN PART: "Smithies [or "Gems," "Thin-Tex," or "Seal-Test"] Prophylactics," "Liquid Latex," or "Dr. Robinson #333 Disease Preventative * * * Wilson-Robinson Co. Incorporated Boston, Mass."

NATURE OF CHARGE: Adulteration, Section 501 (c), the strength of the article differed from, and its quality fell below, that which it purported and was represented to possess. (Samples of the article were found to be defective because of the presence of perforations or holes.)

Misbranding, Section 502 (a), certain statements on the labels and on the article, which represented and suggested that the article was a prophylactic for protection against disease in man and would be efficacious in the prevention of disease in man, were false and misleading.

DISPOSITION: May 14, 1943, a plea of guilty having been entered, the defendant was fined $5,400.

2322. Adulteration and misbranding of prophylactics. U. S. v. W. H. Reed and Co., Inc., a partnership, and Robert A. Gusman and Jerome Rado. Pleas of guilty. Partnership fined $600; individual defendants each fined $300. (F. D. C. No. 15527. Sample Nos. 67066–F, 87219–F.)

INFORMATION FILED: September 30, 1946, Northern District of Georgia, against W. H. Reed and Co., Inc., Atlanta, Ga., and Robert A. Gusman and Jerome Rado, partners.

ALLEGED SHIPMENT: On or about April 10 and July 18, 1944, from the State of Georgia into the State of Missouri.

LABEL, IN PART: (Packages) "Red-Pak" or "X cello's prophylactics a product of latex Mfd. By The Killian Mfg. Co. Akron, Ohio."

NATURE OF CHARGE: Adulteration, Section 501 (c), the quality of the article fell below that which it purported and was represented to possess. It purported to be and was represented as a prophylactic, but was not a prophylactic since it was ineffective for prophylaxis because of the presence of holes.

Misbranding, Section 502 (a), (1 shipment) the statement "Prophylactics" appearing on the packages containing the article was false and misleading.

DISPOSITION: March 6, 1947. Pleas of guilty having been entered, the partnership was fined $600 and the individual defendants were each fined $300.

2323. Adulteration and misbranding of prophylactics. U. S. v. 348 Gross * * *. (F. D. C. No. 24611. Sample No. 22388–K.)

LIBEL FILED: April 29, 1948, Northern District of Texas.

ALLEGED SHIPMENT: On or about February 10, 1948, by W. H. Reed & Co., Inc., from Atlanta, Ga.

PRODUCT: 348 gross of rubber *prophylactics* at Dallas, Tex. Examination of samples showed that 2.2 percent were defective in that they contained holes.

LABEL, IN PART: (Box) "Golden Pheasant This package contains three Golden Pheasant Prophylactics."

NATURE OF CHARGE: Adulteration, Section 501 (c), the quality of the article fell below that which it purported and was represented to possess.

Misbranding, Section 502 (a), the representation on the label to the effect that the product would be effective for the prevention of disease was false and misleading as applied to an article containing holes.

DISPOSITION: June 7, 1948. W. H. Reed & Co., Inc., claimant, having consented to the entry of a decree, judgment of condemnation was entered and the product was ordered released under bond for segregation and conversion of the unfit portion into scrap rubber, under the supervision of the Federal Security Agency.

2324. Adulteration and misbranding of prophylactics. U. S. v. 118 Gross * * * (and 1 other seizure action). (F. D. C. Nos. 23014, 23632. Sample Nos. 66699–H, 86713–H.)

LIBELS FILED: May 7 and August 12, 1947, Eastern District of Missouri and Eastern District of Pennsylvania.

ALLEGED SHIPMENT: On or about August 5, 1946, and July 7, 1947, by Killashun Sales Division, from Akron, Ohio.

PRODUCT: *Prophylactics.* 118 gross at St. Louis, Mo., and 21 gross at Philadelphia, Pa. Examination of samples showed that 4 percent in one lot and 4.5 percent in the other lot were defective in that they contained holes.

LABEL, IN PART: "Tetratex [or "Texide"] Prophylactics."

NATURE OF CHARGE: Adulteration, Section 501 (c), the quality of the article fell below that which it purported and was represented to possess.

Misbranding, Section 502 (a), the label statements "Prophylactic" and "Prophylactics tested" were false and misleading as applied to an article containing holes.

DISPOSITION: June 6, 1947, and January 19, 1948. Default decrees of condemnation and destruction.

2325. Adulteration and misbranding of prophylactics. U. S. v. 42 Gross * * *. (F. D. C. No. 21834. Sample No. 50132–H.)

LIBEL FILED: December 12, 1946, Southern District of Texas.

ALLEGED SHIPMENT: On or about July 11, 1946, by the Killashun Sales Division, from Akron, Ohio.

PRODUCT: 42 gross of rubber *prophylactics* at Houston, Tex. Examination of samples showed that 4 percent were defective in that they contained holes.

LABEL, IN PART: "Apris Prophylactics."

NATURE OF CHARGE: Adulteration, Section 501 (c), the quality of the article fell below that which it purported and was represented to possess.

Misbranding, Section 502 (a), the label statements "Prophylactic" and "Prophylactics" were false and misleading as applied to an article containing holes.

DISPOSITION: January 31, 1947. Default decree of condemnation and destruction.

2326. Adulteration and misbranding of prophylactics. U. S. v. 311 Gross * * *. (F. D. C. No. 24628. Sample No. 30329–K.)

LIBEL FILED: May 11, 1948, Southern District of California.

ALLEGED SHIPMENT: On or about April 5, 1948, by the Rexall Drug Co., from St. Louis, Mo.

PRODUCT: 311 gross of rubber *prophylactics* at Vernon, Calif. Examination of samples showed that 2.4 percent were defective in that they contained holes.

LABEL, IN PART: "Roger (O.K.) Prophylactic Manufactured by Roger Rubber Products Inc., Los Angeles, Calif."

NATURE OF CHARGE: Adulteration, Section 501 (c), the quality of the article fell below that which it purported and was represented to possess.

Misbranding, Section 502 (a), the label statement "Prophylactic" was false and misleading as applied to an article containing holes.

DISPOSITION: June 15, 1948. Default decree of condemnation and destruction.

2327. Adulteration and misbranding of prophylactics. U. S. v. 144½ Gross * * *. (F. D. C. No. 23801. Sample No. 24704–K.)

LIBEL FILED: October 9, 1947, District of Minnesota.

ALLEGED SHIPMENT: On or about September 9 and 17, 1947, by the Dean Rubber Manufacturing Co., from North Kansas City, Mo.

PRODUCT: 144½ gross of rubber *prophylactics* at Minneapolis, Minn. Examination of samples showed that 9 percent were defective in that they contained holes.

LABEL, IN PART: "Dean's Peacocks."

NATURE OF CHARGE: Adulteration, Section 501 (c), the quality of the article fell below that which it purported and was represented to possess.

Misbranding, Section 502 (a), the label statement "Tested * * * An Aid in Preventing Venereal Disease" was false and misleading as applied to an article containing holes.

DISPOSITION: April 21, 1948. Default decree of destruction.

2328. Adulteration and misbranding of prophylactics. U. S. v. 120 Gross * * *. (F. D. C. No. 19810. Sample No. 51406–H.)

LIBEL FILED: May 1, 1946, District of Minnesota.

ALLEGED SHIPMENT: On or about January 22 and March 15, 1946, by the Dean Rubber Manufacturing Co., from North Kansas City, Mo.

PRODUCT: 120 gross of *prophylactics* at Minneapolis, Minn. Examination of samples showed that 3.7 percent were defective in that they contained holes.

LABEL, IN PART: "Dean's Peacocks."

NATURE OF CHARGE: Adulteration, Section 501 (c), the quality of the article fell below that which it purported and was represented to possess.

Misbranding, Section 502 (a), the label statements "Tested on New, Modern Equipment for Your Protection * * * An Aid in Preventing Venereal Diseases" were false and misleading as applied to an article containing holes.

DISPOSITION: The Dean Rubber Manufacturing Co., claimant, filed an answer denying that the product was adulterated or misbranded, and on September 13, 1946, it filed a motion for an order requiring the Food and Drug Administration to deliver a portion of the official sample, remaining untested, to enable the claimant to make an adequate test thereof. After consideration of the arguments and briefs of counsel with respect to the motion, the court handed down, on March 11, 1947, the following decision in denial of the motion:

NORDBYE, *District Judge:* "This is a libel proceeding commenced by an information. The claimant brings this motion for an order requiring the Federal Security Agency of the Food and Drug Administration at Minneapolis, Minnesota, to deliver on payment therefor a sufficient number of prophylactics from the official sample remaining untested to enable the claimant to make an adequate test thereof, or, in the alternative, in the event such part of the official sample is not furnished that the proceeding be dismissed with prejudice.

"Involved in this proceeding are 120 gross of rubber prophylactics. The Food and Drug Administration took an official sample of one and one-half gross prior to the seizure on May 3, 1946. On August 9, 1946, the claimant requested in writing that four dozen of prophylactics out of the official sample of one and one-half gross be turned over to it for analysis, and offered to pay for the same. The request of the claimant has been denied. The reason assigned is that the entire official sample taken by the Government has been used in testing and analysis and no part of the sample which was taken remains. Claimant bases its right to a part of the official sample for analysis under Section 372 (b), 21 U. S. C. A., which reads as follows:

> Where a sample of a food, drug, or cosmetic is collected for analysis under this Act the Secretary shall, upon request, provide a part of such official sample for examination or analysis by any person named on the label of the article, or the owner thereof, or his attorney or agent; except that the Secretary is authorized, by regulations, to make such reasonable exceptions from, and impose such reasonable terms and conditions relating to, the operation of this subsection as he finds necessary for the proper administration of the provisions of this Act.

"Under Section 371, 21 U. S. C. A., the Administrator is specifically given authority to promulgate regulations for the efficient enforcement of the Act and pursuant to this authority the Administrator has promulgated regulations under the sampling provisions of the Act. These regulations provide that, when a sample is collected for analysis, examination, and tests under the Act, it shall be designated as an official sample, and it is then provided

> (b) When an officer or employee of the Department collects an official sample of a food, drug, or cosmetic for analysis under the Act, he shall collect at least twice the quantity estimated by him to be sufficient for analysis, unless
> * * *
> (2) the costs of twice the quantity so estimated exceeds $10; * * *
> (c) After the Food and Drug Administration has completed such analysis of an official sample of a food, drug, or cosmetic as it determines, in the course of analysis and interpretation of analytical results, to be adequate to establish the respects, if any, in which the article is adulterated or misbranded within the meaning of the Act, or otherwise subject to the prohibitions of the Act, and has reserved an amount of the article it estimates to be adequate for use as exhibits in the trial of any case that may arise under the Act based on the sample, a part of the sample, if any remains available, shall be provided for analysis, upon written request, by any person named on the label of the article, or the owner thereof, or the attorney or agent of such person or owner, * * *.

"The Government objects to the motion on the grounds that (1) the statute referred to and the regulations promulgated thereunder refer only to 'a food, drug, or cosmetic' and that a rubber prophylactic must be considered to be a 'device' under the Act, United States v. 43½ Gross Rubber Prophylactics, 65 F. Supp. 534, 535, aff'd March 4, 1947, Circuit Court of Appeals, Eighth Circuit, and therefore is not covered by the Act referred to, and that (2) under Section b (2) of the regulations above quoted, it was not necessary for the Department to collect a quantity in excess of that estimated to be sufficient for analysis by the Government.

"It is the Government's position that, when Congress enacted Section 372 (b), 21 U. S. C. A., and used the terms 'food, drug, or cosmetic,' it did so deliberately, and under Section 321, 21 U. S. C. A., the term 'drug' is specifically defined as 'articles intended for use in the * * * prevention of disease in man * * * but does not include devices or their components, parts, or accessories.' The Government reasons that the omission of 'devices' from Section 372 (b), 21 U. S. C. A., was not an oversight but was done deliberately because 'devices' are generally bulky and expensive, and that it would not be practical to obtain samples of 'devices' in quantities which would be adequate for the inspection of both parties. Claimant, however, urges that the term 'drug' as used in Section 372 (b) includes the term 'device' and that the Food and Drug Department has heretofore construed the term 'drug' as including rubber prophylactics.

"Under the circumstances herein, however, I do not find it necessary to pass on the first objection to claimant's motion because, under the regulations promulgated by the Administrator, the motion must be denied. So far as the record herein indicates, the sample of one and one-half gross was the estimated quantity necessary for analysis by the Government. The showing is that this entire quantity was in fact used for this purpose and is no longer in existence in that by reason of the tests and analysis made by the Government, the entire sample was necessarily destroyed. Under the regulations, it was incumbent upon 'an officer or employee of the Department' to collect 'twice the quantity estimated by him to be sufficient for analysis' unless 'the cost of twice the quantity so estimated exceeds $10.' In response to the motion herein, the Government has filed an affidavit from which it appears that the one and one-half gross taken by the Government as a sample for the purpose of analysis cost $7.05. Twice the cost of the official sample totals $14.10, which, of course, is in excess of the $10 limitation provided in Section (b) 2 hereinbefore recited.

"The Department was under no obligation to permit the claimant to examine any part of the sample which it needed for its own analysis. When a sample is obtained, the Department has no means of knowing whether any claimant will request an examination of the official sample or not. Undoubtedly that fact prompted the Administrator to provide that, where the cost of twice the quantity estimated to be sufficient for analysis exceeds $10, no obligation rests on the officer or employee of the Department to collect twice the quantity. True, the claimant has to make advance payment of the cost of the part of the official sample requested by it for analysis, but the item of initial outlay by the Department is a matter of importance because the Department has no means of knowing whether any demand for inspection will be made by claimant, and therefore has no means of knowing whether any part of the expense in purchasing a sample will be defrayed by the claimant. It appears from the showing herein that, under the regulations, by reason of the cost of the quantity estimated to be sufficient for analysis, it was not necessary for the Government to purchase twice the quantity, and it further appearing that the entire sample has been used for making such analysis and is no longer in existence, it must follow that, if for no other reason, the motion must be denied. It may be pointed out in passing that, by reason of the stipulation entered into between the parties under date of June 10, 1946, and an order of Court made thereon, both the libelant and the claimant were authorized to withdraw representative samples of the property and merchandise seized, not to exceed two gross each, for the purpose of examination, testing and analysis. While the samples thus withdrawn do not constitute a part of the official sample, the claimant must content itself under the circumstances herein with such sample for the purpose of examination, testing and analysis.

"The motion of the claimant is therefore denied. An exception is reserved to the Claimant."

On April 17, 1948, the claimant having withdrawn its answer and consented to the entry of a decree, judgment was entered ordering that the product be destroyed.

2329. Adulteration and misbranding of prophylactics. U. S. v. 38 Gross * * *. (F. D. C. No. 24637. Sample No. 18962–K.)

LIBEL FILED: May 14, 1948, Southern District of Ohio.

ALLEGED SHIPMENT: On or about February 9, 1948, by the Latex Distributing Co., from Chicago, Ill.

PRODUCT: 38 gross of rubber *prophylactics* at Cincinnati, Ohio. Examination of samples showed that 3.4 percent were defective in that they contained holes.

LABEL, IN PART: "Tetratex Prophylactic Mfd. By L. E. Shunk Latex Prod. Inc. Akron, Ohio."

NATURE OF CHARGE: Adulteration, Section 501 (c), the quality of the article fell below that which it purported and was represented to possess.

Misbranding, Section 502 (a), the label statements "Prophylactic," "Prophylactics," and "Germ Proof" were false and misleading as applied to an article containing holes.

DISPOSITION: June 18, 1948. Default decree of condemnation and destruction.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF FALSE AND MISLEADING CLAIMS*

DRUGS FOR HUMAN USE

2330. Misbranding of Radium Ore, Colwell's Penetrating Healing Balm, and Radium Bath Powder. U. S. v. Carry Grace Colwell (Colwell Radium Company). Plea of not guilty. Tried to the jury. Verdict of guilty. Fine, $500, and probation for 2 years. (F. D. C. No. 21481. Sample Nos. 53096–H, 59069–H to 59071–H, incl.)

INFORMATION FILED: July 23, 1947, District of Minnesota, against Carry Grace Colwell, also known as Mrs. J. H. Colwell, trading as the Colwell Radium Company, St. Paul, Minn.

ALLEGED SHIPMENT: From the State of Minnesota into the States of Ohio and Montana. The products were shipped on or about August 29 and September 20, 1946, and were accompanied by letters addressed to the consignees and by circulars entitled "Colwell Radium Co. Manufacturers of the World's Greatest Healing Remedies."

PRODUCT: Analyses showed that the *Radium Ore* consisted of a yellow and gray rock resembling carnotite, with a radium concentration in one portion of 30 parts per billion, and in another portion of 50 parts per billion; that the *Colwell's Penetrating Healing Balm* was a yellow ointment consisting essentially of glycerin, water, and paraffin, small amounts of borax and perfume, and a negligible radium content; and that the *Radium Bath Powder* was a mixture of magnesium sulfate and sodium sulfate, with small amounts of borax, carnotite, and perfume, and a radium concentration of 1 part per billion.

NATURE OF CHARGE: *Radium Ore.* Misbranding, Section 502 (a), certain statements in the labeling of the article were false and misleading, since they represented and suggested that the article would have a cleansing effect; that it would be helpful to most every ailment of the human body; that it would be a potent treatment for many stomach and intestinal disorders; that it would produce cell action and assist the organs of the body; that it would be efficacious in the cure, mitigation, and treatment of serious gland trouble; that it would build glands; that it was one of the world's greatest healing remedies; that it would be efficacious in the removal of cancer tumors; and that it would be efficacious in the cure, mitigation, and treatment of poliomyelitis (infantile paralysis), prostatic obstruction, gout, rheumatism, lumbago, sciatica, arthritis, neuritis, neuralgia, Bright's disease, liver disorders, high blood pressure, eczema, psoriasis, chronic skin disorders, obesity, chronic diarrhea, gastrointestinal disorders, fermentation, gastric dyspepsia, heart trouble, tonsil trouble, sinus trouble, hay fever, gall bladder trouble, kidney trouble, appendicitis, anemia, impotency, premature old age, paralysis, nervousness, gastric ulcers, nephritis, insomnia, flatulence, goiter, constipation, locomotor ataxia, diabetes, tuberculosis, asthma, bronchial trouble, tumors, and bone infection. The article would not have a cleansing effect; it would not be a potent treatment for many stomach and intestinal disorders; it would not produce cell action and assist the organs of the body; it was not one of the world's greatest healing remedies; it would not build glands; and it would not be efficacious for the other purposes represented.

Colwell's Penetrating Healing Balm. Misbranding, Section 502 (a), certain statements in the labeling of the article were false and misleading, since they represented and suggested that the article was a penetrating healing balm; that it would be efficacious in the cure, mitigation, and treatment of sore muscles, aches, and pains; that it would build tissue, relax the nerves, and relieve sinus colds, skin infection, arthritis, neuritis, sciatica, rheumatism, swelling and inflammatory conditions, sinus, heart, and lung troubles, chronic appendicitis, menses, varicose veins, and similar ailments; and that it would be efficacious in the cure, mitigation, and treatment of serious gland trouble, and would build the glands. The article was not a penetrating healing balm, and it would not be efficacious for the purposes represented.

Radium Bath Powder. Misbranding, Section 502 (a), certain statements in the labeling of the article were false and misleading, since they represented

*See also Nos. 2301–2308, 2310, 2311, 2316, 2317, 2319–2329.

and suggested that the article would build the glands and that it would be efficacious in the cure, mitigation, and treatment of serious gland trouble, inflammatory and sciatic conditions, neuritis, lumbago, gout, arthritis and other forms of rheumatism, low vitality, cancer, tumors, appendicitis, diabetes, la grippe, high blood pressure, varicose veins, eczema, syphilis, erysipelas, scarlet fever, smallpox, prostatic obstruction, poliomyelitis, and alcoholic and cigarette poisoning. The article would not build glands, and it would not be efficacious for the purposes represented. Further misbranding, Section 502 (b) (1), the article failed to bear a label containing the name and place of business of the manufacturer, packer, and distributor; and, Section 502 (b) (2), it failed to bear a label containing an accurate statement of the quantity of the contents, since it bore no label containing a statement of the quantity of the contents.

DISPOSITION: A plea of not guilty having been entered, the case came on for trial before a jury on November 21, 1947. The jury returned a verdict of guilty on December 1, 1947; on December 16, 1947, the court imposed a fine of $250 on each of counts 1 and 2, suspended the imposition of sentence on counts 3 and 4, and placed the defendant on probation for a period of two years, conditioned that she bring the labeling of her products into compliance with the law.

2331. Misbranding of Fernel Intestinal Normalizer, Vitalgen, Fernel Slenda Creme, Fernel Obesine No. 1, Endogene, Slimming T-Ade, Climacteric No. 149, Roxor, Goat's Milk Capsules, Calcium Carduus Compound, Nedra, Linol, Neo-Serum Solution of Organic Marine Substances, Prostate Suppository, and Saw Palmetto & Silica Co. U. S. v. Dr. Jean Paul Fernel. Plea of not guilty. Tried to the jury. Verdict of guilty. Defendant sentenced to 1 year's imprisonment on each of 21 counts, with the sentence on counts 1, 2, and 3 running consecutively, the sentence on the remainder of the counts running concurrently with count 3, and the sentence on count 1 running concurrently with the sentence in a previous case. (F. D. C. No. 12547. Sample Nos. 15028-F to 15034-F, incl., 15037-F to 15039-F, incl., 49061-F, 49062-F, 49068-F, 52045-F, 54825-F, 57840-F, 59563-F, 59571-F, 60323-F, 67410-F, 72020-F.)

INFORMATION FILED: August 21, 1944, Northern District of Illinois, against Dr. Jean Paul Fernel, Chicago, Ill.

ALLEGED SHIPMENT: Between the approximate dates of December 31, 1943, and February 23, 1944, from the State of Illinois into the States of California, Indiana, Massachusetts, Wisconsin, Colorado, Maryland, Michigan, Ohio, and Missouri.

PRODUCT: Analyses disclosed that the *Fernel Intestinal Normalizer* consisted of capsules containing agar, Irish moss, bile extract, and nucleic acid-containing material such as duodenal extract; that the *Vitalgen* consisted essentially of magnesium chloride; that the *Fernel Slenda Creme* consisted essentially of ammonium carbonate, gum, and water, and perfumed and colored with a red dye; that the *Climacteric No. 149* consisted of tablets containing plant material and alkaloids, including strychnine, berberine, aconitine, hydrastine, and milk sugar; that the *Roxor* consisted of capsules containing essentially glandular material, dulse, zinc phosphide, and talc; that the *Goat's Milk Capsules* consisted essentially of milk sugar, fat, protein, a small proportion of a calcium compound, and water; that the *Fernel Obesine No. 1* consisted of capsules containing plant material, including dulse, bladder-wrack, and glandular material; that the *Endogene* consisted of capsules containing glandular material and plant material, including dulse; that the *Slimming T-Ade* consisted essentially of sassafras bark and orange peel; that the *Prostate Suppository* consisted essentially of ichthammol, benzocaine, and plant material, including belladonna and Hyoscyamus incorporated in a fatty acid base; that the *Saw Palmetto & Silica Co.* consisted of tablets containing plant material, milk sugar, and minute quantities of calcium sulfate and calcium fluoride; that the *Calcium Carduus Compound* consisted of tablets containing calcium sulfide, milk sugar, and small amounts of extracts of plant drugs; that the *Nedra* consisted of capsules containing glandular material, plant material, a small proportion of zinc phosphide, and talc; that the *Linol* consisted of linseed oil; and that the *Neo-Serum Solution of Organic Marine Substances* consisted essentially of water containing small proportions of organically combined iodine and sulfur, sodium iodide, and sodium chloride.

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements on the labels of the articles and in accompanying circulars entitled "Beauty-Health News" were false and misleading, since the articles would not be effective for the purposes claimed. The false and misleading statements regarding the articles were to the following effect:

That the *Fernel Intestinal Normalizer* would be efficacious in normalizing the intestinal secretion and function; that it would aid intestinal digestion; that it would be an adequate and competent treatment for colitis and the similar chronic eczema, and other skin conditions;

That the *Vitalgen* would supply the user with the essential halogen salts; that it would be efficacious in the cure, mitigation, treatment, and prevention of liver and gall-bladder sluggishness by promoting normal bile flow; that it was a systemic food which would aid in generating a normal inner vitalizing force; that it would aid liver elimination and detoxication, and would aid in preventing the formation of gallstones and in their expulsion after they had been formed; that it would aid, nourish, and improve the function of the endocrines and other glandular structures, the nervous system, and the brain; that it would aid in nervous conditions, improve the general nervous tone, bring about a state of calm serenity, and aid in avoiding a nervous breakdown; that it would aid in clearing the complexion, give luster to the eyes, and sheen and life to the hair; and that it would aid in the treatment of acne, psoriasis, chronic eczema, and other skin conditions;

That the *Fernel Slenda Creme* would be efficacious in stimulating fat absorption by its action through the skin; that it would aid in promoting the slimming processes of the body where it was applied; that it would aid in absorption of fat deposits around the chin, at the back of the neck, around the breasts where they seem oversized, the arms, the hips, and the abdomen, and wherever fat deposits had accumulated and a streamlined appearance was desired;

That the *Fernel Obesine No. 1* would be efficacious as an aid in the type of obesity where fat deposits are all over the body, including forearms, wrists, hands, legs, ankles, and back of the neck;

That the *Endogene* would aid in revitalizing and normalizing the endocrine system, including the endocrines of the generative system; that it would aid in preventing a nervous breakdown and other nervous irregularities; and that it would aid in renewing the zest of life;

That the *Slimming T-Ade* would be a slimming aid; that it would remove craving for fattening starches and sweets during a slimming regimen; and that it would be a preventive aid against nutritional obesity;

That the *Climacteric No. 1/9* would be efficacious in the cure, mitigation, treatment, and prevention of symptoms associated with the climacteric and menopause;

That the *Roxor* would be efficacious as an aid for the relief of symptoms of the male climacteric, including loss of energy, vitality, and zest of life;

That the *Goat's Milk Capsules* would be efficacious in the cure, mitigation, treatment, and prevention of gastric ulcers, colitis, intestinal fermentation, constipation, hyperacidity, and autointoxication; that they would promote better health; that they were the chief source of fluorine; and that fluorine is a youth and beauty aid;

That the *Calcium Carduus Compound* would be efficacious as an aid and relief in varicose veins and ulcerous conditions;

That the *Nedra* would be efficacious as an aid in promoting growth and development of the mammary glands and their surrounding tissue by its tonic influence, and that it would be efficacious in normalizing the feminine glandular system in cases of small undeveloped breast;

That the *Linol* would be efficacious in the prevention of habitual colds and acute catarrhal conditions of the upper respiratory passages, and that it would aid in the treatment of such conditions;

That the *Neo-Serum Solution of Organic Marine Substances* would be efficacious in revitalizing and rejuvenating the body, and that it would be efficacious in overcoming the symptoms of premature aging;

That the *Prostate Suppository* would be efficacious in the cure, mitigation, treatment, and prevention of disease conditions of the prostate;

That the *Saw Palmetto & Silica Co.* would be efficacious in the cure, mitigation, treatment, and prevention of subacute and chronic prostatitis and chronic prostatitis in the aged.

Further misbranding, Section 502 (e) (1), the *Linol* was not designated solely by a name recognized in an official compendium, and its label failed to bear its common or usual name, linseed oil.

DISPOSITION: A plea of not guilty having been entered, the case came on for trial before a jury, at the conclusion of which trial, on December 5, 1944, the jury returned a verdict of guilty. On December 29, 1944, the court denied the defendant's motion for a new trial and sentenced him to one year's imprisonment on each of the 21 counts of the information, with the sentence on counts 1, 2, and 3 to run consecutively, the sentence on the remainder of the counts to run concurrently with that on count 3, and the sentence on count 1 to run concurrently with the 1 year sentence imposed in the case reported in notices of judgment on drugs and devices, No. 1560.

2332. Alleged misbranding of Body Cell Salts. U. S. v. Kirkpatrick Laboratories, Inc., and Dr. George Kirkpatrick. Pleas of not guilty. Tried to the jury. Counts 1 and 3 dismissed. Verdict of guilty against the corporation on count 4. Disagreement on verdict with respect to both defendants on count 2 and with respect to individual on count 4. Motion of defendants for acquittal granted. (F. D. C. No. 15502. Sample No. 60500–F.)

INFORMATION FILED: May 24, 1945, District of Oregon, against Kirkpatrick Laboratories, Inc., Portland, Oreg., and Dr. George Kirkpatrick.

ALLEGED SHIPMENT: On or about April 28, 1944, from the State of Oregon into the State of California.

PRODUCT: Analysis of a sample of the article showed that *Solution A* consisted essentially of water, small proportions of compounds of calcium, iron, and sodium, chloride and sulfate, and traces of compounds of aluminum, magnesium, and silicon. Phosphorus was not present. *Solution B* consisted essentially of water, small proportions of compounds of calcium, sodium, and potassium, iodide and chloride, and traces of silicon and sulfate.

LABEL, IN PART: "8 Fluid Oz. Body Cell Salts * * * (Solution 'A') [or '(Solution 'B')"] Kirkpatrick Laboratories ,Inc., 603 Panama Bldg. Portland Oregon." A circular entitled "Method of Administering Body Cell Salts" accompanied the product.

NATURE OF CHARGE: Misbranding, Section 502 (a), the name on the label and in the circular, "Body Cell Salts," was false and misleading, in that it represented and suggested that the drugs contained mineral ingredients in the proper proportions to build up and maintain the cells of the body, whereas the drugs would not be effective for such purpose. Certain statements on the labels and in the circular represented and suggested that *Solution "A"* contained salts which would aid in preserving physiological alkalinity, in promoting metabolism, in stimulating nutrition, and in maintaining normal body function, and that when used in conjunction with another drug known as *Solution "C,"* it would assist in supplying the deficiency existing when a bronchial condition was present; that *Solution "B"* contained salts which would aid in supplying a deficiency of the elements necessary to restore normal functions of the body; and that *Solution "A"* and *Solution "B"* when used in conjunction with each other, would assist in supplying the deficiency existing when a chronic or subacute condition other than a bronchial condition was present. It was alleged that the drugs would not be effective for the purposes claimed.

Further misbranding, Section 502 (a), the statements on the labels, (*Solution "A"*) "Contains the following ingredients: Aluminum, Carbonate, Chlorine, Calcium * * * Magnesium, Natrium, Phosphate, Sulphur, Silica" and (*Solution "B"*) "Contains the following ingredients: Carbonate, Calcium, Chlorine * * * Natrium, Potassium, Sulphur, Silica," were false and misleading, in that the statements represented and suggested that the articles contained the ingredients listed in therapeutically important amounts, whereas the *Solution "A"* contained no phosphate, and the articles contained therapeutically inconsequential amounts of the other stated ingredients.

The products were alleged also to be misbranded under the provisions of the law applicable to foods, as reported in notices of judgment on foods.

DISPOSITION: Pleas of not guilty having been entered on behalf of the defendants, the case came on for trial before a jury on or about March 24, 1947. During the trial, the court dismissed counts 1 and 3 of the information, ruling that the products were not foods. Motions for a judgment of acquittal were made by

the defendants at the conclusion of the Government's case and, again, at the conclusion of the defendant's case. These motions were argued and were denied by the court. The case was submitted to a jury and a verdict of guilty was returned against the company on count 4, but the jury was unable to agree on a verdict on count 2 with respect to either defendant, or on a verdict on count 4 with respect to Dr. Kirkpatrick.

On March 31, 1947, the defendants again filed a motion for acquittal on counts 2 and 4 on the grounds, among others, that the defendants had requested to be furnished with a part of the official sample; that the Government had refused the request for the reason that the owner of the solutions had declined to give the Government more than 2 ounces of each of the products; and that all had been consumed by the Government in its tests. The defendants, in their motion, argued that the law requires that the Government take twice the amount required for its tests; that there remained in the possession of the person from whom the samples were collected at least 6 ounces of each drug; that the Government had the power to seize the drugs if necessary; and that failure to furnish a part of the official samples had prejudiced the defendants in their defense. On the same date, the court granted the motion of acquittal on counts 2 and 4, holding both defendants not guilty on those counts.

2333. Misbranding of Biosol and Urosol. U. S. v. Warren S. Piper (Merit Remedy Co.). Plea of guilty. Fine, $300. (F. D. C. No. 23218. Sample Nos. 15126–H, 53317–H, 67118–H.)

INFORMATION FILED: September 22, 1947, Southern District of Ohio, against Warren S. Piper, trading as the Merit Remedy Co., Dayton, Ohio.

ALLEGED SHIPMENT: On or about May 17 and 20 and July 11, 1946, from the State of Ohio into the States of Illinois, Kansas, and Indiana.

PRODUCT: Examination disclosed that the *Biosol* consisted essentially of water, alcohol, esters, bile salts, soap, phenolphthalein, and aromatics; and that the *Urosol* consisted essentially of water, alcohol, strontium bromide, potassium acetate, sodium benzoate, sugar, aromatics, and plant extractives, including a small amount of unidentified alkaloids.

NATURE OF CHARGE: *Biosol.* Misbranding, Section 502 (a), certain statements on the label of the article were false and misleading, since they represented and suggested that the article would be efficacious in the treatment of liver and gall disorders and conditions resulting from liver and gall disorders, whereas the article would not be efficacious for such purposes. Further misbranding, Section 502 (a), certain statements in the labeling of a portion of the article, i. e., a leaflet entitled "Instructions for Taking Biosol," which was shipped with the article, a letter dated July 11, 1946, a leaflet entitled "Diet Suggestions," and circulars entitled "Biosol A Remedy of Merit," "The Sick Gall Bladder," and "Urosol A Remedy of Merit," which were sent to the consignee on or about July 12, 1946, were false and misleading, since the article would not be effective for the purposes, and would not fulfill the promises of benefit, suggested and implied by the statements. The statements represented and suggested that the article was a solvent of the bile; that it would be efficacious in correcting ailments caused by liver and gall disorders; that it would be efficacious in the cure, mitigation, and treatment of gallstone disease, stomach and bowel ailment, gas and colic pains, disturbances incidental to liver and gall irregularities, liver and gall troubles, infected catarrhal gall bladder and ducts, thickened and stagnant bile, and kidney trouble; that use of the article would make an operation unnecessary; that the article would remove the cause of gall trouble; that it would be efficacious in the cure, mitigation, and treatment of inflammation of the gall bladder and ducts, pus in the gall bladder, distress and pain in pit of stomach, chronic dyspepsia, indigestion, sour stomach, heartburn, a feeling like a weight or heavy load in the stomach, a feeling like a heavy band around the waist, pain in right side or between or under shoulder blades, shifting or shooting pains around the waistline, burning sensation in right side just below the ribs, sick headache, colic, constipation, diarrhea, blues, piles, yellow, sallow, blotched, itchy skin, gas in stomach and bowels, loss of memory, lack of energy and vitality, gloomy depressed feeling, irritability, constant desire to sigh, poor circulation, cold hands and feet, gas pains under heart, dizzy spells, jaundice, vertigo, dull, heavy feeling in head, bad dreams and nightmare, nausea and vomiting of bile, a constant metallic or bitter taste in mouth, blood poison caused

by fermentation of food, dull, periodical headaches, pus formations, and arthritis; that it would restore health; that it was a liver tonic; that it possessed powerful healing properties; that when used alone and in conjunction with *Urosol*, it would be efficacious in the cure, mitigation, and treatment of conditions in which the kidneys and the bladder are affected by bile; that it would banish the symptoms caused by liver and gall disorders; that it would cleanse out the liver and gall bladder; that it would be efficacious in restoring the sick gall bladder to its normal condition; that it was a wonderful remedy for gall stones; and that it would be efficacious in the cure, mitigation, and treatment of gallstones, infected gall bladder, and all forms of gall bladder and liver troubles.

Urosol. Misbranding, Section 502 (a), certain statements on the label of the article, and in a circular entitled "Urosol A Remedy of Merit," which was shipped on or about the same date that the article was shipped, were false and misleading, since the article would not be effective for the purposes, and would not fulfill the promises of benefit, suggested and implied by the statements. The statements represented and suggested that the article would aid in the relief of cystitis, and prostate, bladder, and urinary inflammation; that it would be efficacious in the promotion of the free and natural flow of the urine and in the relief of congestion in the urinary passages; that it would be efficacious in the treatment of prostate gland troubles and inflammation of the bladder and kidneys; that it would produce a general healthy condition throughout the urinary tract; that it was a specific and regulator to the entire urinary tract; that it would be efficacious in the treatment of persons who suffer from bile backing into the kidney; that it would be efficacious in the cure, mitigation, and treatment of prostatitis, inflammation of the urethra, inflammation and pus in the kidneys, rising at night to void the urine, frequent desire to pass urine during the day, difficulty in passing the urine, passing of urine accompanied with a burning sensation, sciatic pains in the legs, pains at the back of the neck, aches through the hips and pelvic region, worries, irritability, whitish discharge in the urine, partial or complete impotence, lack of sexual desire, disturbance of the digestion, difficulty in passing stool, piles, general disturbances of the nervous system, and general lack of vigor; and that it would be efficacious in the cure, mitigation, and treatment of pains in the back, leg pains, loss of pep, lumbago, swollen feet and ankles, rheumatic pains, and dizziness. Further misbranding, Section 502 (e) (2), the article was not designated solely by a name recognized in an official compendium and was fabricated from two or more ingredients, and its label failed to bear a statement of the quantity and proportion of strontium bromide which was present in the article.

DISPOSITION: November 3, 1947. A plea of guilty having been entered, the court imposed a fine of $100 on each of the 3 counts of the information.

2334. Misbranding of B_1 and iron tablets. U. S. v. Paul Case. Plea of guilty. Fine, $250. (F. D. C. No. 20209. Sample Nos. 4162–H, 4605–H.)

INFORMATION FILED: February 18, 1947, District of Massachusetts, against Paul Case, Brockton, Mass.

ALLEGED SHIPMENT: On or about January 26 and June 11, 1945, from the State of Massachusetts into the State of New Jersey.

PRODUCT: Analysis disclosed that the product consisted of orange, sugar-coated tablets, containing compounds of iron and calcium, phosphates, lactates, and thiamine.

LABEL, IN PART: "The Paul Case B–1 and Iron Tablets A Doctor's Formula Formula—Number 3."

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements in a letter shipped with the article were false and misleading, since they represented and suggested that the article would restore and maintain pep and vitality; that it would be efficacious in treating persons who are tired, run-down, and worn-out; that it would restore the energy to work; and that it would make one look and feel younger and bring about abounding health. The article would not accomplish the results claimed.

DISPOSITION: March 15, 1948. A plea of guilty having been entered, the court imposed a fine of $250.

2335. Misbranding of Key-Mins. U. S. v. Edward T. Keenan (Keenan Laboratories). Plea of nolo contendere. Fine, $100. (F. D. C. No. 21446. Sample No. 7603-H.)

INFORMATION FILED: May 28, 1947, Southern District of Florida, against Edward T. Keenan, trading as Keenan Laboratories, Frostproof, Fla.

ALLEGED SHIPMENT: On or about July 2, 1945, from the State of Florida into the State of New York.

LABEL, IN PART: "Key-Mins Citrate and Phosphate Crystals Contain Dicalcium Phosphate and the Citrates of Iron, Magnesium, Potassium, Manganese, Copper, Zinc, Nickel and Cobalt for Dietary use * * * Approximate Milligrams per Gram Calcium 153.540 Phosphorus 118.620 Iodine .015 Iron 1.050 Copper .301 Manganese .475 Magnesium 31.630 Potassium 7.909 Cobalt .155 Zinc .315 Nickel .158 Vitamin B-1 (Thiamine Hydrochloride) .158 Vitamin B-2 (Riboflavin) .316 Vitamin B-6 (Pyrodoxine Hydrochloride) .031 Nicotinic Acid 2.372 Calcium Pantothenate .079."

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements in a leaflet entitled "Bulletin XXI," which was shipped with the article, were false and misleading. These statements represented and suggested that the article would be efficacious in the treatment and prevention of colon stasis, urine difficulties, sour stomach, indigestion, menstrual pains, celiac disease, colitis, diabetes, influenza, coryza, rheumatic fever, and dyskinesia; that it would improve the quality and increase the quantity of intestinal chyme; that it would enable the pancreas and liver to perform their functions; that it would improve digestion and the actions of the digestive juices; and that it would prepare the intestinal content for evacuation. The article would not be efficacious for such purposes.

Further misbranding, Section 502 (a), certain statements on the label of the article were misleading, since they represented and suggested that the article was of nutritional significance by reason of its content of manganese, magnesium, potassium, cobalt, zinc, nickel, vitamin B_6, and calcium pantothenate, whereas the article was not of any nutritional significance by reason of its content of such ingredients.

The article was alleged also to be misbranded under the provisions of the law applicable to foods, as reported in notices of judgment on fods.

DISPOSITION: December 31, 1947. A plea of nolo contendere having been entered, the court imposed a fine of $100.

2336. Misbranding of Nature's Minerals Compound and vitamin B complex tablets. U. S. v. Nature's Mineral Food Co., a partnership, and Perry B. Smith. Pleas of guilty. Partnership fined $500; individual fined $100. (F. D. C. No. 20162. Sample Nos. 16633-H, 16634-H, 17225-H.)

INFORMATION FILED: October 2, 1946, Southern District of Indiana, against Nature's Mineral Food Co., Indianapolis, Ind., and Perry B. Smith, a partner.

ALLEGED SHIPMENT: On or about March 19 and April 12, 1945, from the State of Indiana into the State of Illinois. Accompanying the products were form letters bearing the heading "Good Morning," circulars entitled "Are You Suffering From Mineral Starvation," and leaflets entitled "Cause and Results," "Prostate Glands," "Testimonials for Nature's Minerals Rheumatism," and "Abundant Health."

Analysis showed that the *Nature's Minerals Compound* consisted essentially of calcium, sodium, iron, magnesium, sulfates, phosphates, chlorides, carbonates, free sulfur, and a trace of iodides, and that the *vitamin B complex tablets* contained thiamine chloride, nicotinic acid, and riboflavin.

LABEL, IN PART: "Nature Minerals Compound," or "High Potency Vitamin B Complex."

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements in the labeling were false and misleading. These statements represented and suggested and created in the mind of the reader the impression that the articles, used alone or in conjunction with each other, would be benefical in the treatment of enlarged, sluggish, and dormant prostate glands, stagnant blood, and impaired nervous energy; that they would enable the body to throw off accumulated toxic acid poisons; that they would keep hundreds out of hospitals and would keep men past 40 happy and vigorous; that they would be beneficial in the treatment of any disease conditions of the prostate glands in young or old men,

whether acute or of long standing; that they would restore the prostate glands to a normal state of vigor and vitality and would eliminate the need for an operation on those glands; that they would purify and improve the quality and the quantity of the blood; that they would restore the normal functioning of the organs and the nervous system; that they would produce healthy bodies and would enable the body to get rid of accumulated poisons and acids in the system; that they would enable the body to throw off any disease with which it was inflicted; that they would be beneficial in the treatment of arthritis, and when combined with vitamins would produce wonders in the system; that they would enable one to regain health and would cause one to retain health; that they would be efficacious in the correction of poor teeth, bone diseases, deformities, lack of energy, lowered vitality, Bright's disease, tuberculosis, colds, lowered resistance, swollen and enlarged glands, bunions, inflammatory conditions, patches of grayish white and membranous substances in the throat, skin discharges and eruptions, stuffy colds, dark brown circles under the eyes, pain accompanied by swelling, thick white coating on the tongue, sluggish liver, sick headache, belching, deafness with crackling noises, and deep barking cough; that they would prevent eruptive diseases in early childhood; that they would create and maintain cell life in the structures of the nerves and brain; that they would be efficacious in the correction of nervous debility, neuralgia, nervous headache, hysteria, melancholia, excessive shyness, liability to faint, irregular pulse, palpitation of the heart, undue sensitiveness to noises, inability to concentrate, irritability, sleeplessness, mania, cramps, nerve pains, constipation from spasmodic nervousness, twitching muscles, mental illusions, dyspepsia with gas, hiccoughs, stuttering, and many other painful conditions; that they would control waste matter such as pus, perspiration, and excess water; that they would prevent infections, rheumatism, arthritis, gallstones, hay fever, sinus trouble, and diabetes; that they would neutralize acids and keep the lime in solution; that they would be beneficial in the treatment of pimples, boils, carbuncles, styes, and abscesses; that they would eliminate every ache and pain and would insure perfect bodily functioning; that they would be beneficial in the treatment of asthma; that they would restore normal alkalinity to the body; that they would eliminate disease regardless of its name, whether it was chronic or acute; that they would build up greater resistance to disease and senility; that they would correct disturbed mineral balance; that they would be beneficial in the treatment of ulcers, neuritis, and kidney and intestinal troubles; that they would insure abundant health and would provide abundant energy; that they would activate and revive glands and would remove waste matter and poisons from the tissues of the blood stream; and that they would destroy disease of every organ of the body. The articles, when used alone or in conjunction with each other, would not be effective for the purposes so represented.

The articles were alleged also to be misbranded under the provisions of the law applicable to foods, as reported in notices of judgment on foods.

DISPOSITION: December 5, 1946. Pleas of guilty having been entered, the partnership was fined $500 and the individual defendant was fined $100.

2337. Misbranding of Nu-Youth Hormone Creme. U. S. v. 1,945 Jars * * *. (F. D. C. No. 23885. Sample No. 2610–K.)

LIBEL FILED: November 4, 1947, District of Columbia.

ALLEGED SHIPMENT: On or about August 28, 1947, by Kathryn, Inc., from Chicago, Ill.

PRODUCT: 1,945 1¼-ounce jars of *Nu-Youth Hormone Creme* at Washington, D. C.

LABEL, IN PART: "Nu-Youth Hormone Day or night Creme."

NATURE OF CHARGE: Misbranding, Section 502 (a), the term "Nu-Youth" was false and misleading, in that it suggested that the article would be effective in renewing the attributes of youth in the mature user, whereas it would not be effective for that purpose; and the label statements "Contains 7,500 international units (per ounce) of Gynestrol (Trade Mark) natural estrogen (estrone-estrodiol-equilin-equilinin) [female hormones]" was false and misleading, since the potency of the article was equivalent to not more than 1,500 International Estrone Units per ounce.

DISPOSITION: December 30, 1947. Default decree of condemnation. The product was ordered delivered to a public institution for the use of that institution.

2338. Misbranding of Viavi Capsules, Viavi Liquid, and Viavi Emulsion. U. S. v. 75 Packages, etc. (F. D. C. No. 20557. Sample Nos. 42020–H to 42022–H, incl.)

LIBEL FILED: July 22, 1946, District of Columbia.

PRODUCT: 575 packages of *Viavi Capsules*, 900 bottles of *Viavi Liquid*, and 100 bottles of *Viavi Emulsion*, which were in interstate commerce in the District of Columbia, in the possession of the Eastern Viavi Co., Washington, D. C.

LABEL, IN PART: "Viavi Capsules * * * Contains actively, Viavi (specially prepared Hydrastine, Berberine, Canadine), Oxyquinolin Benzoate, Tannin," "Viavi Liquid Contains actively, Viavi (specially prepared Hydrastine, Berberine, Canadine), Tincture Capsicum, Poke Root, Glycerine," or "Viavi Emulsion * * * Contains actively, Mineral Oil, Hydrastine and Berberine in Extract of Hydrastis, Colloidal Kaolin."

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements on the labels of the articles and in accompanying booklets entitled "How to Use Viavi," "What Viavi Is," "The Truth About Laxatives," "Are You on the Borderline," and "A Helping Hand to Health" were false and misleading. These statements represented and suggested that *Viavi Capsules* and *Viavi Liquid* were effective to relieve congestion and establish better circulation in mucous membranes; that *Viavi Capsules* were effective to relieve congested conditions of pelvic mucous membranes and adjacent tissues; that *Viavi Liquid* was effective to relieve dullness of hearing due to a catarrhal type of congestion in the ear or relieve profuse secretion, congestion, and soreness through the pelvic region; and that *Viavi Emulsion* was effective to sooth the irritated colon membranes and remove or destroy bacterial poisons and irritants from the intestines. The articles were not effective for the purposes represented.

DISPOSITION: The Eastern Viavi Co., claimant, having applied for removal of the case for trial to the Eastern District of Wisconsin, an order was entered on September 10, 1946, directing such removal. On April 5, 1948, the claimant having consented to an entry of a decree, judgment of condemnation was entered and the products were ordered released under bond for relabeling under the supervision of the Federal Security Agency.

2339. Misbranding of sassafras root bark. U. S. v. 20 Cartons * * *. (F. D. C. No. 21040. Sample No. 53043–H.)

LIBEL FILED: September 24, 1946, Northern District of Ohio.

ALLEGED SHIPMENT: On or about March 30, 1946, By C. Lee Tea Co., from Huntington, W. Va.

PRODUCT: 20 cartons, each containing 25 ½-ounce packages, of sassafras root bark at Akron, Ohio.

LABEL, IN PART: "Red Sass-Frass Tea."

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements on the labels of the article and in a circular enclosed with the article were false and misleading, since they represented and suggested that the article was effective to maintain health and would be effective in the treatment, prevention, and cure of ague, colds, scurvy, chronic rheumatism, skin disease, and syphilis. The article would not be effective for such purposes.

DISPOSITION: December 11, 1947. The C. Lee Tea Co. having filed an answer, but having failed to appear at the trial of the case, judgment of condemnation was entered and the product was ordered destroyed.

2340. Misbranding of Egyptian Herb Tea. U. S. v. 59 Boxes * * * and 1,500 Circulars. (F. D. C. No. 23681. Sample No. 89530–H.)

LIBEL FILED: September 9, 1947, District of South Dakota.

ALLEGED SHIPMENT: On or about May 27, 1947, by the Egyptian Tea Co., from Akron, Ohio.

PRODUCT: 59 2-ounce boxes of *Egyptian Herb Tea* at Huron, S. Dak., together with 1,500 circulars entitled, "Egyptian Herb Tea A Natural Laxative." Examination showed that the product consisted essentially of plant material, including a laxative drug such as senna.

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements in the circulars were false and misleading, since they represented that the article was safe; that it was a cure for constipation; and that it would promote sleep, soothe the nerves, clean the intestines, and digest food. The article was not safe and would not fulfill the promises of benefit stated and implied.

DISPOSITION: October 21, 1947. Default decree of condemnation and destruction.

2341. Misbranding of Sul-Ray Colloidal Sulphur Mineral Baths. U. S. v. 218 Cartons * * *. (F. D. C. No. 18266. Sample No. 21361–H.)

LIBEL FILED: On or about November 6, 1945, Western District of Missouri.

ALLEGED SHIPMENT: On or about March 9, 1944, by the Sante Chemical Co., from New York, N. Y.

PRODUCT: 218 cartons of *Sul-Ray Colloidal Sulphur Mineral Baths* at Kansas City, Mo. Examination disclosed that the product consisted essentially of sodium sulfate, carbonate and phosphate, borax, and sulfur.

NATURE OF CHARGE: Misbranding, Section 502 (a), the labeling of the article was false and misleading in the same respect as that of the article in the case reported in notices of judgment on drugs and devices, No. 2283.

DISPOSITION: January 11, 1946. Default decree of destruction.

2342. Misbranding of Durmaseptic. U. S. v. 37 Cartons * * * and 43 Posters. (F. D. C. No. 23853. Sample No. 24005–K.)

LIBEL FILED: October 17, 1947, Western District of Wisconsin.

ALLEGED SHIPMENT: On or about August 15 and 22, 1947, by Durma Products Co., Minneapolis, Minn.

PRODUCT: 37 dozen cartons, each containing 1 jar, of *Durmaseptic* and 43 posters entitled "Here's Guaranteed Relief for Athletes Foot and other Skin Irritations," at La Crosse, Wis. The article consisted essentially of aspirin, methyl salicylate, and eugenol in an ointment base.

LABEL, IN PART: (Jar) "Durmaseptic * * * Active Ingredients: Acetylsalicylic Acid, Methyl Salicylate, Eugenol—in a suitable base."

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements on the carton, on the jar and circular enclosed in the carton, and on a poster were false and misleading, since such statements represented and suggested that the product would be effective in the treatment of acne, burns, callouses, itching and burning dermatitis, all fungous infections, including jungle rot and ringworm, dandruff, psoriasis, arthritis, rheumatism, and boils and impetigo, and that it would be effective for local application to the skin in treating skin disorders. The product would not be effective for such purposes.

Further misbranding, Section 502 (b) (2), the carton label failed to bear an accurate statement of the quantity of the contents; and, Section 502 (e) (2), the label failed to bear the common or usual name of each active ingredient, since no statement of ingredients appeared on the carton label, and on the jar label acetylsalicylic acid had not been declared by its common or usual name, aspirin.

DISPOSITION: December 5, 1947. Default decree of forfeiture and destruction.

2343. Misbranding of Cloro devices. U .S. v. Lawrence P. Dickey (The L. P. Dickey Co.) Plea of nolo contendere. Imposition of sentence suspended and defendant placed on probation for 6 months. (F. D. C. No. 23567. Sample No. 40688–H.)

INFORMATION FILED: October 7, 1947, District of Arizona, against Lawrence P. Dickey, trading as the L. P. Dickey Co., Tucson, Ariz.

ALLEGED SHIPMENT: On or about July 25, 1946, from the State of Arizona into the State of Missouri.

PRODUCT: This device was essentially an electrolytic cell for the manufacture of chlorine gas, with a motor and fan for blowing the gas out of an aperture.

LABEL, IN PART: "Cloro Roh Radio Co. * * * Tucson, Arizona."

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements in the circular entitled "Here's to Your Health," which was received from the defendant by the consignee at approximately the time of the receipt of the devices, were false and misleading. These statements represented and suggested that the devices would be efficacious in the treatment of sinus, arthritis, hay fever,

bronchitis, and common colds, and that the devices were used by leading medical clinics throughout the country. They would not be efficacious in the treatment of such disease conditions, and they were not in use in the leading medical clinics throughout the country.

DISPOSITION: October 22, 1947. A plea of nolo contendere having been entered, the court suspended the imposition of sentence and placed the defendant on probation for 6 months.

2344. Misbranding of Thermapax device. U. S. v. Duval B. Jackson. Plea of nolo contendere. Sentence of 30 days in jail and fine of $200. (F. D. C. No. 23251. Sample Nos. 21995–H, 21996–H.)

INFORMATION FILED: December 29, 1947, Northern District of Indiana, against Duval B. Jackson, Memphis, Tenn.

ALLEGED SHIPMENT: On or about February 27 and March 12, 1946, from the State of Indiana into the States of Tennessee and Kentucky.

PRODUCT: Examination showed that the device was a cap-shaped metal shell containing insulated wire. When connected to a source of electric current, it produced heat and was surrounded by a magnetic field.

LABEL, IN PART: "Thermo-Magno-Ray Thermapax Health Applicator."

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements in accompanying circulars entitled "Magnetic Rays A Powerful Factor in Restoring and Preserving Health," which were delivered to the consignees of the device on or about February 27 and March 7, 1946, were false and misleading. These statements represented and suggested that the device would be efficacious in restoring and preserving health; that it would produce health giving rays; that it would be efficacious in the treatment and prevention of human ills and would accomplish brilliant results in the treatment of disease; that it would be efficacious in the cure, mitigation, and treatment of electrical deficiency in the blood, autointoxication, myriad manifestations of toxemia, most chronic ailments, and many acute conditions; that it would keep the white cells active in fighting disease organisms in the blood stream; that it would energize the body tissue and normalize metabolism processes; that it would enable one to have more energy, more life, and more pep; that it would induce activity in the circulatory system; that it would stimulate natural vital processes; that it would promote elimination of waste; that it would strike at the underlying cause of disease; that it would set antitoxic and eliminative forces and organs to work, would enable them better to perform their functions, and would cause all the life forces to work towards health; that it would provide renewed health and vigor; that it would increase the power of the body to rid itself of the waste matter and poisons which clog the cells and blood stream more and more with advancing years; that it would be efficacious in the cure, mitigation, treatment, and prevention of faulty elimination of poisons which result from abnormal activities of the organs, tissues, and cells of the body; that it would be efficacious in preventing the absorption of poisons produced by putrefactive changes in the intestinal contents; that it would be efficacious in overcoming the effects of poisons from infected teeth, tonsils, and sinuses, and the effects of infections such as colds, influenza, and pneumonia; that it would be efficacious in the cure, mitigation, treatment, and prevention of toxemia resulting from overeating, improper diet, overindulgence in cigarette smoking, worry, fear, coffee drinking, and alcohol; that it would influence favorably the fundamental activities of the body such as circulation, elimination, digestion, nutrition, and metabolism; that it would be efficacious in developing and maintaining a state of exuberant health; that it would be efficacious in keeping one physically and mentally fit; and that it would be efficacious in the cure, mitigation, and treatment of asthma, arthritis, sinusitis, light and heavy colds, "strep" or sore throat, acute bronchitis, pleurisy, lumbago, acute pains and aches due to influenza, pain in the appendix area, enlarged or inflamed prostate, painful and difficult menstruation, steptococcus and staphylococcus infections, chronic sinus conditions, pains in the area of the sinuses and shoulders due to infected teeth, digestive distress caused from gas, high blood pressure, tic douloureux trifacial neuralgia, impotence in men, ovarian distress, bleeding external hemorrhoids, and diabetes. The device would not be effective for the purposes, and would not fulfill the promises of benefit, stated and implied.

DISPOSITION: In accordance with Rule 20 of the Federal Rules of Criminal Procedure, the case was transferred to the Western District of Tennessee for the entry of a plea and sentence. On February 18, 1948, the defendant entered a plea of nolo contendere and received a sentence of 30 days' imprisonment on each of the 2 counts of the information, to run concurrently, and was fined $100 on each of the 2 counts.

2345. Misbranding of Tou-Ray Health Lamps. U. S. v. 10 Tou-Ray Health Lamps, etc. (F. D. C. No. 23712. Sample No. 73531–H.)

LIBEL FILED: September 18, 1947, Northern District of Ohio.

ALLEGED SHIPMENT: On or about February 25, 1947, by the Touraine Co., from Trenton, N. J.

PRODUCT: 10 *Tou-Ray Health Lamps* at Akron, Ohio, together with 130 circulars entitled "Tou-Ray Health Lamp and what it means to you." Examination showed that the devices were floor-type lamps equipped with both the ordinary incandescent bulbs and a source of ultraviolet light.

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements in the circulars were false and misleading, since they represented and suggested that the lamps would be effective to give health, sterilize the air, prevent airborne infections, and clear skin lesions, whereas the lamps would not be effective for such purposes.

DISPOSITION: January 8, 1948. Default decree of condemnation and destruction.

DRUGS FOR VETERINARY USE*

2346. Misbranding of Poultry Pep, Poultry-Ton and Conditioner for Poultry, Chick-Ton, Pheno Nox-Ide-Tabs, and Large Round Worm Powder. U. S. v. Hobbs & Co., Walter C. Hobbs, and Mason B. Hobbs. Pleas of guilty. Fine of $250 and costs against the defendants jointly. (F. D. C. No. 23213. Sample Nos. 22763–H to 22765–H, incl., 34949–H to 34951–H, incl., 35981–H, 35982–H.)

INFORMATION FILED: December 8, 1947, District of Kansas, against Hobbs & Co., a partnership, Kansas City, Kans., and Walter C. Hobbs and Mason B. Hobbs, members of the partnership.

ALLEGED SHIPMENT: On or about March 14 and April 2 and 6, 1946, from the State of Kansas into the States of Illinois and Missouri.

PRODUCT: Analyses disclosed that the *Poultry Pep* was an aqueous solution containing principally magnesium sulfate, alum, and salt, with smaller amounts of iron, manganese, and chromium compounds; that the *Poultry-Ton and Conditioner for Poultry* was a mixture containing chiefly iron sulfate, copper sulfate, and magnesium sulfate, and smaller amounts of zinc sulfate, and plant material including nux vomica; that the *Chick-Ton* was a mixture of iron sulfate, copper sulfate, sulfur, sodium bicarbonate, and plant material including nux vomica; that the *Pheno Nox-Ide-Tabs* consisted of a green compressed tablet containing chiefly zinc sulfate, sodium, alum, and boric acid, and a small amount of zinc phenolsulfonate; and that the *Large Round Worm Powder* was a gray powder consisting chiefly of copper sulfate, iron sulfate, and magnesium sulfate, with smaller amounts of quassia, nux vomica, kamala, and areca nut.

LABEL, IN PART: "The Hobbs Gold Bond Poultry Pep," "Gold Bond Poultry-Ton and Conditioner For Poultry," "Judge Hobbs' Gold Bond Chick-Ton," "The Hobbs Pheno Nox-Ide-Tabs," or "Gold Bond Large Round Worm Powder."

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements on the respective labels and in leaflets entitled "Gold Bond Products Used and Sold by the World's Largest Baby Chick Producers," in letters addressed "Dear Poultry Friend" mailed to the consignees of the *Poultry-Ton* and the *Chick-Ton* about two days subsequent to the shipment of the drugs, and in a leaflet entitled "Why Buy Feed for Germs and Worms?" shipped with the *Large Round Worm Powder* were false and misleading, since the articles would not be effective to accomplish the purposes represented and suggested.

The false and misleading representations in the labeling were to the following effect:

*See also No. 2310.

That the *Poultry Pep* would be efficacious to stimulate poultry; that it would minimize the danger of infection and digestive disorders; that it would be a treatment for diseased conditions of poultry; that it would correct abnormal conditions of fowls; that it would be efficacious as a healing agent for poultry; that it would be beneficial for fowls of all ages; that it would assist in the healing of inflamed parts; and that it would combat disease spreading to other fowls;

That the *Poultry-Ton and Conditioner for Poultry* would be efficacious to combat infestation of large round worms; that it would keep fowls tuned up; that it would assist birds in maintaining vigor and health; that it would be efficacious as a conditioner and would promote thriftiness and appetite; that it would be efficacious in the treatment of chicken pox or sorehead, fowl cholera, typhoid and liver trouble, leukemia, paralysis of poultry, and tracheitis of poultry; that it would rebuild vitality of depleted fowl's system caused by worm infestation; that it would be efficacious to combat infestations; that it would clear the blood stream of impurities; and that it would combat diseases;

That the *Chick-Ton* would be efficacious to control and combat simple bowel disorders; that it would be efficacious as an aid in treating aspergillosis and brooder pneumonia, and in the treatment of coccidiosis; that it would be efficacious to combat the miseries of chicks; that it would be efficacious against worms; that it would be an aid to health; and that it would be a remedy for diarrhea;

That the *Pheno Nox-Ide-Tabs* would be of value in the prevention and treatment of disease conditions of fowls; and,

That the *Large Round Worm Powder* would be an effective treatment for large roundworms, and that it would be efficacious to combat large roundworms, tapeworms, and pinworms, and worms and germs of the intestinal tract of poultry.

Further misbranding, the statements "Copper Sulphate 25%" on the label of the *Poultry-Ton and Conditioner for Poultry* and "Copper Sulphate 38%" on the label of the *Chick-Ton* were false and misleading, since the articles contained less copper sulfate than so represented.

DISPOSITION: January 5, 1948. Pleas of guilty having been entered, the court imposed a fine of $50 on each of the 5 counts of the information, together with costs, against the defendants jointly.

2347. Misbranding of Mar-to-Ma Compound Powder, Mar-to-Ma Chick Rem, Mar-to-Ma Mycro Rem, and Mar-to-Ma Broiler Compound Powder. U. S. v. Thomas H. Speigelmire (T. H. Speigelmire & Son). Plea of nolo contendere. Fine, $500 on count 1; imposition of sentence suspended on counts 2, 3, and 4, and defendant placed on probation for 2 years. (F. D. C. No. 21483. Sample Nos. 5268–H to 5270–H, incl., 56675–H.)

INFORMATION FILED: June 4, 1947, Middle District of Pennsylvania, against Thomas H. Speigelmire, trading as T. H. Speigelmire & Son, Selinsgrove, Pa.

ALLEGED SHIPMENT: On or about March 19 and April 10, 1946, from the State of Pennsylvania into the States of New Jersey and Massachusetts.

PRODUCT: Analyses disclosed that the *Mar-to-Ma Compound Powder* was a brown powder containing about 13.2 percent anhydrous magnesium sulfate and 4.26 percent phenothiazine, in addition to sodium, manganese, iron, sulfur, sulfate, and carbonates; that the *Mar-to-Ma Chick Rem* was a coarse heterogeneous mixture containing not more than a trace, or no phenothiazine, with epsom salt, acetic acid, or acetates, asafetida, sulfur, sulfates, potassium, and magnesium; that the *Mar-to-Ma Mycro Rem* was a heterogeneous mixture containing about 0.160 percent phenothiazine, 10.7 percent copper sulfate, 14.3 percent magnesium sulfate, and acetic acid, or acetates, asafetida, sulfur, sulfates, potassium, and a greenish-brown organic material; and that the *Mar-to-Ma Broiler Compound Powder* was a heterogeneous mixture containing about 4.36 percent phenothiazine, sodium sulfate, sulfur, magnesium sulfate (epsom salt), charcoal, iron oxide, and tomato peelings, with traces of magnesium compound and yeast.

NATURE OF CHARGE: *Mar-to-Ma Compound Powder.* Misbranding, Section 502 (a), certain statements in the labeling, namely, the label, a letter addressed to the consignee, a booklet, and circulars entitled "Mar-To-Ma Remedies and Feeds," "Feeding Chart," and "Supplement to Feeding Chart," which letter, booklet, and circulars were mailed on the same day that the product was

shipped, were false and misleading, since the statements represented and suggested that the article would be efficacious to develop the reproductive organs of poultry for heavy laying; to produce more eggs from hens and to produce healthy, heavy laying birds; to build health in horses, cows, sheep, pigs, dogs, cats, chickens, poults, turkeys, ducks, geese, foxes, and mink; to exterminate and eliminate worms of all kinds; to build up a good rich blood stream; to regulate and keep the liver and kidneys healthy; to purify the blood and to build a strong healthy body in hens; and, further, that the article would be a preventive and remedy for white and yellow diarrhea, leg weakness, blackhead in turkeys, and coccodiosis in chickens; that it would be efficacious against causes of range paralysis of poultry; and that it would keep dogs well and in good health. The article would not be efficacious for the purposes represented.

Mar-to-Ma Chick Rem. Misbranding, Section 502 (a), certain statements in the above-described labeling were false and misleading, in that they represented and suggested that the article would be efficacious as a preventive of disease in poultry and animals; that it would be efficacious in keeping the bowels of laying hens and turkeys in good condition and in treating farm stock and pigs for disorders of the bowels; that it would be efficacious in the treatment of diarrhea, scours, and similar conditions in animals; that it would be efficacious to create an appetite and enable birds to digest their food; that it would cause birds to develop better; that it would be efficacious in the treatment of coccidiosis and blackhead; that it would be efficacious to produce healthy, heavy laying birds, and to prevent and remedy white and yellow diarrhea; that when used in combination with the *Mar-To-Ma Compound Powder*, it would prevent and remedy leg weakness, blackhead in turkeys, coccidiosis in chickens, toxic poison of the liver, and range paralysis caused by worms; that it would rid birds of worms and prevent enlarged liver; that it would be efficacious to cure coccidiosis and blackhead, and to kill germs, including germs in the bowel; and that it would heal the bowels and would bring birds back to normal health. The article would not be efficacious for such purposes.

Mar-to-Ma Mycro Rem. Misbranding, Section 502 (a), certain statements in the above-described labeling were false and misleading, in that they represented and suggested that the article would be efficacious in the cure, mitigation, and treatment of mycosis, gizzard erosin, and feed and mold poisoning; that it would be efficacious in the treatment of birds which are low in spirit, drag their wings, and have loose bowels, with yellow, greenish-white, and thin "runny" droppings; and that the article would be efficacious to put birds back on the road to health. The article would not be efficacious for such purposes.

Mar-To-Ma Broiler Compound Powder. Misbranding, Section 502 (a), certain statements on the label of the article, and in a leaflet entitled "How to Prevent Coccidiosis, Blackhead, Mycosis * * * and Colds," which leaflet was shipped with the article, were false and misleading, since such statements represented and suggested that the article would be efficacious as an aid in the treatment of disordered bowels; that it would assist in eliminating some of the worms from which poultry and livestock suffer; that it would be efficacious to cause chicks to grow much faster than they would under ordinary conditions; and that it would be efficacious to produce fast growth in turkeys. The article would not be efficacious for such purposes.

DISPOSITION: January 19, 1948. A plea of nolo contendere having been entered, the court imposed a fine of $500 on count 1 of the information, suspended the imposition of sentence on counts 2, 3, and 4, and placed the defendant on probation for 2 years.

2348. Misbranding of Tone-O-Mor, Mor-O Liquid, and Bro-No-Mor. U. S. v. 6 Packages, etc. (F. D. C. No. 23876. Sample Nos. 87001–H to 87003–H, incl.)

LIBEL FILED: October 29, 1947, Northern District of Iowa.

ALLEGED SHIPMENT: From Minneapolis, Minn., by Hilltop Laboratories. The products were shipped on or about October 24, 1946, and March 8, 1947, and the printed matter was shipped on or about November 7, 1946, and during the month of March 1947.

PRODUCT: 6 4-pound packages of *Tone-O-Mor*, 6 1-quart bottles of *Mor-O Liquid*, and 10 1-quart bottles of *Bro-No-Mor* at Hospers, Iowa, together with one poster entitled "Step Up Egg Production and Hatchability" and two magazines entitled "Hilltop Poultry News Broadway Issue 1947, Vol. V, No. 1." Analyses showed that the *Tone-O-Mor* was a mixture of iron oxide, epsom salt, ferrous sulfate, copper sulfate, sulfur, plant matter, and small amounts of alkaloids, including strychnine; that the *Mor-O Liquid* was essentially an acid liquid containing tannin extracts, aromatic substances, and lactic acid; and that the *Bro-No-Mor* was essentially a kerosene emulsion containing camphor, guaiacol, eucalyptol, other phenolic substances, and water.

NATURE OF CHARGE: *Tone-O-Mor.* Misbranding, Section 502 (a), the name of the article and certain statements in its labeling were false and misleading, since the name and statements represented and suggested that the article was effective to promote growth and hatchability, to aid poultry health, to step up egg production, and to keep birds laying and healthy. The article would not be effective for the purposes stated and implied.

Mor-O Liquid. Misbranding, Section 502 (a), certain statements in the labeling were false and misleading, since they represented and suggested that the article was effective in the treatment of noninfectious enteritis; that it was effective to aid poultry health and to keep poultry laying and healthy; and that it contained 100 percent active ingredients. The article was not effective for such purposes, and it did not contain 100 percent active ingredients.

Bro-No-Mor. Misbranding, Section 502 (a), certain statements in the labeling were false and misleading, since they represented and suggested that the article when used as directed was effective in the treatment of simple noninfectious conditions of the upper respiratory tract of poultry; and that it would be effective to aid poultry health, to prevent and combat respiratory trouble, to keep poultry laying and healthy, and to aid in loosening accumulated mucous in the nose and throat. The article when used as directed was not effective for such purposes.

DISPOSITION: November 25, 1947. Default decree of condemnation and destruction.

2349. Misbranding of Tropiodin Colloidal Iodine (jelly paste form and liquid form) and misbranding of Chloro-Iodine. U. S. v. 45 Jars, etc. (F. D. C. No. 21972. Sample Nos. 38897–H to 38899–H, incl.)

LIBEL FILED: December 16, 1946, Eastern District of Wisconsin.

ALLEGED SHIPMENT: 9 jars of the *Tropiodin Colloidal Iodine* (jelly paste form) were secured from Albert B. Trencavel, doing business as the Neodyne Company, Chicago, Ill., and transported from Chicago to Pewaukee, Wis., in the automobile of Jack H. Schmutzler during the month of July 1946. All other jars of the product were shipped by M. T. Edwards, under the direction of Albert B. Trencavel, doing business as the Neodyne Company, from Ashland, Va., to Pewaukee, Wis., on or about September 9, 1946. The *Tropiodin Colloidal Iodine* (liquid form) and the *Chloro-Iodine* were purchased by Jack H. Schmutzler from Albert B. Trencavel, doing business as the Tropiodin Company, Chicago, Ill., and transported from Chicago to Pewaukee in the automobile of Jack H. Schmutzler on or about October 31, 1946. A quantity of printed matter relating to the products was shipped by Albert B. Trencavel, senior trustee and president of the Trencavel Company, Chicago, Ill., from Chicago to Jack H. Schmutzler, Pewaukee, Wis., on or about July 23 and September 13, 1946.

PRODUCT: 68 jars of *Tropiodin Collodial Iodine* (jelly paste form), 153 bottles of *Tropiodin Collodial Iodine* (liquid form), and 177 bottles of *Chloro-Iodine* at Pewaukee, Wis., together with 1,075 copies of a circular entitled "Tropiodin," 400 blotters bearing the words "Directions for use of Tropiodin," and 300 circulars entitled "(Non-Specific) Chloro-Iodine." The jars were 1-, 2½-, and 4-ounce sizes, and the bottles were 4-, 8-, and 16-fluid ounce sizes. Analysis of the *Tropiodin Colloidal Iodine* products showed that they consisted chiefly of water, starch, iodine, and potassium iodide; and that the *Chloro-Iodine* consisted chiefly of glycerin, iodine, potassium and sodium iodides and chlorides, and water.

NATURE OF CHARGE: *Tropiodin Colloidal Iodine* (liquid form and jelly paste form). Misbranding, Section 502 (a), certain statements in the circulars entitled "Tropiodin" and in the blotters were false and misleading. These

statements represented and suggested that the articles when used as directed would be efficacious in the treatment of mastitis, contagious abortion, sterility, Johne's disease, and infections in goats and cows; that they would be effective for cuts, sores, swollen udders, inflammations, and bruises in animals; that they would be effective antiseptics and bactericides for intravenous, intramuscular, and subcutaneous injections, and for the mucous membrane in general; that when used as directed the articles would be effective in destroying disease-producing germs; that they would be effective in combating inflammation and in detoxifying tissues and body fluids; that they would promote toxin removal by deeply stimulating the lymphatic system; that they would be effective in reducing fever and would interfere with the progress of disease; that they would be efficacious in the treatment of infections in general and diseases due to improper nutrition, feed conditions, or inflammation; that the articles when used as directed would be efficacious in the treatment of acute and chronic mastitis in cows and goats; that they would be efficacious in the treatment of pneumonia in cows and bulls, shipping fever, milk fever, white scours, sterility, toxic infections, and inflammatory and bacterial conditions; that the articles when used as directed would be efficacious in the treatment of endometritis, cervicitis, vaginitis, Brucella abortus, Trichomonas, Corynebacteria infection, cystic degeneration of the ovaries, and pyometra; that they would be efficacious in the treatment of various causes of abortion and sterility; that they would be efficacious in the treatment and eradication of trichomoniasis in cattle, and in the treatment of wooden tongue and timber tongue in cases of actinomycosis. The articles when used as directed would not be effective in the treatment of the diseases, conditions, and symptoms stated and implied. Further misbranding, Section 502 (a), certain statements on the label of the *Tropiodin Colloidal Iodine* (liquid form) were false and misleading, since they represented and suggested that the article was effective in the treatment in animals of inflammatory processes and infections in general, mastitis, pneumonia, white scours, off-feed conditions, and other infections. The article was not effective in the treatment of such conditions in animals.

Chloro-Iodine. Misbranding, Section 502 (a), certain statements in the circular entitled "(Non-Specific) Chloro-Iodine" were false and misleading. These statements represented and suggested that the article would be effective as an internal and external remedy for better animal health; that when used as directed it would be efficacious in the treatment of infections associated with staphylococci, streptococci, Corynebacteria, abortion bacilli, trichomonads, nematodes, cestodes, trematodes, and other equally virulent and destructive organisms; that it would be effective as an antiseptic, germicide, and vermicide, and as a curative agent in specific diseases; that it would ward off ailments which disastrously ravage animal flesh; that it would be effective in preventing and combating disease in livestock, in preventing contamination and blood poison setting in, and in warding off infection caused by disease germs attacking the body; that it would inhibit sepsis; that when used as directed it would be inimical to all pathogenic organisms that infect the animal body; that when used as directed it would be efficacious in the treatment of mastitis, contagious abortion, sterility, and Johne's disease (paratuberculosis); that it would be effective in the eradication of disease and would maintain resistance to disease; that it would be effective as a prophylactic and healer and as a disinfectant for open sores and inflammatory conditions, abscesses, carbuncles, skin infections of all kinds, and the mucous membrane in general; that it would be effective against all infections of the eye and of the entire genital tract; that it would be effective as a dewormer for goats, sheep, and hogs, and as a bactericide in dysentery of animals; that it would be effective in entirely deworming animals; that it was a specific in destroying the causative germs of dysentery, in eradicating the irritation and inflammation of the intestines, and in stopping diarrhea; that it would be a curative and prophylactic for warding off mastitis, milk fever, dysentery, off-feed conditions, and diseases that originate from improper feeding and bacterial and parasitic invasion; that it would be effective in controlling sterility in cows; that it would be efficacious in the treatment of wooden tongue, timber tongue, endometritis, cervicitis, vaginitis following Brucella abortus (Bang's disease), Trichomonas, and Corynebacteria infection. The article when used as directed would not be effective in the treatment of the diseases, conditions, and symptoms stated and implied.

DISPOSITION: August 11, 1947. Default decree of condemnation and destruction.

2350. Misbranding of Appeteaser. U. S. v. 3,000 Packages * * *. (F. D. C. No. 23931. Sample No. 20928–K.)

LIBEL FILED: November 24, 1947, District of Nebraska.

ALLEGED SHIPMENT: On or about October 1 and 8, 1947, by Hawkeye Sales, Inc., from Des Moines, Iowa.

PRODUCT: 3,000 1½-ounce size packages of *Appeteaser* at Wahoo, Nebr. Analysis showed that the product consisted essentially of iron sulfate, copper sulfate, magnesium sulfate, and small amounts of sodium sulfate and salicylic acid, flavored with anise.

LABEL, IN PART: "Keep Them Eating With Appeteaser Concentrated Powder Form for Feeding Stations and Live Car Shippers * * * For Watering Out: * * * In The Feed."

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements on the label of the article were false and misleading, since they represented and suggested that the article was effective to restore and stimulate the appetites of fowls which were inadequate for any reason, and was effective to increase feed and water consumption of fowls. The article was not effective for such purposes.

DISPOSITION: April 19, 1948. Default decree of condemnation and destruction.

INDEX TO NOTICES OF JUDGMENT D. D. N. J. NOS. 2301 TO 2350

PRODUCTS

[1] (2307, 2330-2332) Prosecution contested.
[2] (2320) Prosecution contested. Contains opinion of the court.
[3] (2328) Seizure contested. Contains opinion of the court.
[4] (2306) Permanent injunction issued.

SHIPPERS, MANUFACTURERS, AND DISTRIBUTORS

[1] (2307, 2330-2332) Prosecution contested.
[2] (2320) Prosecution contested. Contains opinion of the court.
[3] (2328) Seizure contested. Contains opinion of the court.

[1] (2307, 2330-2332) Prosecution contested.
[2] (2320) Prosecution contested. Contains opinion of the court.
[4] (2306) Permanent injunction issued.

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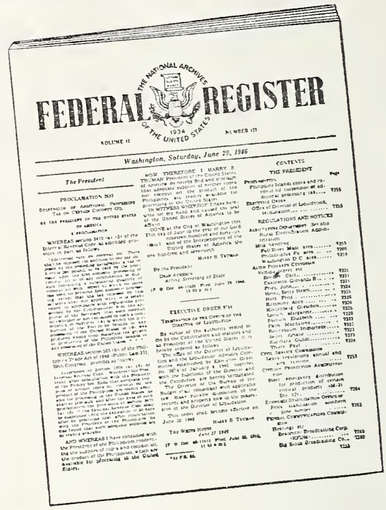

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FOOD AND DRUG ADMINISTRATION

NOTICES OF JUDGMENT UNDER THE FEDERAL FOOD, DRUG, AND COSMETIC ACT

[Given pursuant to section 705 of the Food, Drug, and Cosmetic Act]

2351–2400

DRUGS AND DEVICES

The cases reported herewith were instituted in the United States district courts by the United States attorneys acting upon reports submitted by direction of the Federal Security Administrator.

J. Donald Kingsley, *Acting Administrator, Federal Security Agency.*

Washington, *D. C., October 29, 1948.*

CONTENTS*

NEW DRUG SHIPPED WITHOUT EFFECTIVE APPLICATION

2351. Doctor's Prescription Rx 7–11. U. S. v. 11 Bottles, etc. (F. D. C. 23882. Sample Nos. 16802–K to 16804–K, incl.)

Libel Filed: October 30, 1947, Eastern District of Wisconsin.

Alleged Shipment: On or about May 8, June 5, and July 8 and 19, 1947, by Murrell Laboratories, from Norman, Okla.

Product: 11 1-gallon bottles, 6 cases, each containing 12 1-pint bottles, and 81 cases, each containing 12 8-ounce bottles, of *Doctor's Prescription Rx 7–11* at Milwaukee, Wis.

Nature of Charge: Section 505 (a), the article was a drug which should not have been introduced or delivered for introduction into interstate commerce, since it was a new drug and an application filed pursuant to the law was not effective with respect to the drug. It was a new drug in that its composition consisting essentially of a colored solution containing alcohol, glycerin, sulfanilamide, and sulfathiazole, was not generally recognized among experts qualified by scientific training and experience to evaluate the safety of drugs, as safe for use under the conditions suggested in its labeling, i. e., "Doctor's

*For presence of a habit-forming narcotic without warning statement, see No. 2357; deceptive packaging and imitation of another drug, No. 2376; labeling information not likely to be understood by the ordinary individual under customary conditions of purchase and use, No. 2352; cosmetic, subject to the drug provisions of the Act, No. 2351.

Prescription Seven-11 Guarantee Guaranteed to remove loose dandruff or your money will be refunded. This preparation is not sold as a hair tonic, but is a special prepared medicine and sold only to remove itching, scaly dandruff. Caution: For External Use Only Directions for Treatment Use once a day for four days, then once every other day for one week, or as needed. Apply freely and massage into the scalp. For best results shampoo and dry hair thoroughly before first application. Murrell Laboratories Norman, Oklahoma."

DISPOSITION: February 5, 1948. Default decree of condemnation and destruction.

DRUG REQUIRING CERTIFICATE OR RELEASE, FOR WHICH NONE HAD BEEN ISSUED

2352. Misbranding of penicillin sodium. U. S. v. 77 Cartons, etc. (F. D. C. No. 23648. Sample Nos. 88001–H, 88002–H, 88004–H to 88006–H, incl.)

LIBEL FILED: August 20, 1947, Southern District of New York.

ALLEGED SHIPMENT: On or about May 26 and June 3 and 5, 1947, from Elkins, W. Va., by the Golden Clinic Pharmacy; from Ganado, Ariz., by the Sage Memorial Hospital; from Bradford, Pa., by the Bradford Hospital; from West Chester, Pa., by the Chester County Hospital; from Corpus Christi, Tex., by the Sizer Hospital; and from Washington, D. C., by the Garfield Memorial Hospital. These were returned shipments.

PRODUCT: 77 cartons, each containing 5 200,000-unit vials, and 294 cartons, each containing 5 500,000-unit vials, of *penicillin sodium* at New York, N. Y.

NATURE OF CHARGE: Misbranding, Section 502 (l), the article was represented as a drug composed wholly of penicillin sodium, a derivative of a kind of penicillin, and it was not from a batch with respect to which a certificate or release had been issued pursuant to the law; Section 502 (c), the name and place of business of the manufacturer, packer, or distributor, which is required by law to appear on the label, was not placed on the label in such terms as to render such information likely to be understood by the ordinary individual under customary conditions of purchase and use, since the name and address borne on the label "Proctor Laboratories, 475 Fifth Avenue, New York 17, U. S. A." did not inform the reader that they were not the name and address of the manufacturer but were those of the distributor; and, Section 502 (a), the statements "Lot No. 75," "Lot No. 76," "Lot No. 82," "Lot No. 85," "Lot No. 86" appearing on the labels of various portions of the article were false and misleading, since these statements represented and suggested that the article had been certified by the Food and Drug Administration, Federal Security Agency, under such identifying numbers, when such was not the case.

Further misbranding, Section 502 (a), the labeling of a portion of the article consisting of a circular entitled "Penicillin Sodium-Proctor (Crystalline)" enclosed with the article, giving indications, contraindications, method of preparation of penicillin for treatment, directions for administration, dosage, storage directions, and description of the packaging, was misleading, since such labeling created the impression that the article was crystalline penicillin sodium, whereas the article was amorphous penicillin sodium; and, Section 502 (f) (1), the labeling of two lots of the article failed to bear adequate directions for use.

DISPOSITION: February 6, 1948. Default decree of condemnation. The product was ordered sold to the Heyden Chemical Corp., conditioned that it be redissolved and reprocessed under the supervision of the Food and Drug Administration.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF FAILURE TO BEAR ADEQUATE DIRECTIONS OR WARNING STATEMENTS*

2353. Action to enjoin and restrain the interstate shipment of West's Imported Sea Vegetable Tablets and various other drugs. U. S. v. Mineralized Foods, Inc. (Sea Vegetation Import Co.), and Nathan S. West. Consent decree granting injunction. (Inj. No. 167.)

COMPLAINT FILED: November 21, 1947, District of Maryland, against Mineralized Foods, Inc., also trading as the Sea Vegetation Import Co., Baltimore, Md., and Nathan S. West, president and general counsel of the corporation.

NATURE OF CHARGE: That the defendant had been from time to time introducing and delivering for introduction into interstate commerce quantities of drugs

*See also No. 2352.

composed of so-called "sea vegetation," imported from various foreign countries, in combination with drug chemicals and vitamins, and marketed under the names of *West's Imported Sea Vegetable Tablets, West's Sea-Vo-Kra Tablets, West's D-X Tablets, West's Kalseom Tablets, West's Sodeom Tablets, Ferrolene Tablets, F Y A Tablets, West-Aid Tablets, West-Lax, West's Sea Vegecene (Powder), Mar-Glo Tablets, Ten In One, West-Co, West's Vi-Linn (Choc. Flavored), West's Vi-Linn (Banana Flavored), West's Imported Sea Vegetation Vitaminized,* and *West's Pro-Pi-Pa Tablets.* The products were misbranded within the meaning of Section 502 (f) (1), in that their labeling failed to bear adequate directions for use, since their labeling contained no statement or reference to diseases or conditions for which they were to be used and failed to bear adequate directions for use in all conditions for which they were recommended and suggested in their advertising. The advertising referred to was disseminated and sponsored by the defendants and consisted of a series of lectures conducted by Nathan S. West throughout the United States, and the distribution of the booklet "Excerpts from 'Diet Daily or Die Early'" and other media, in which he recommended and suggested the drugs for use in the treatment, prevention, or cure of arthritis, neuritis, angina pectoris, apoplexy, heart diseases, cerebral hemorrhages, arteriosclerosis, high and low blood pressure, pain in the bones and bone marrow, brain and nerve disturbances, lassitude, nausea, vomiting, headache, sleeplessness, loss of appetite, damage to teeth, cancer, tooth decay, rickets, scurvy, softening of the bones, hairlessness, paralysis, bone and joint disease, malnutrition, leg weakness, roup, stiff neck, beriberi, black tongue, ulcerated gums, falling teeth, sores, dropsy, rheumatism, heart condition, nervousness, frequent colds, kidney conditions, constipation, migraine headache, skin conditions, poor eyesight, hay fever, asthma, sinus infection, continual tiredness, underweight and overweight, stomach and intestinal ulcers, anemia, general weakness, diabetes, painful and irregular menstruation, dropsy, swollen limbs, gall bladder conditions, supersensitivity, brittle fingernails, stiff joints, poor memory, poor circulation, mucous condition, low energy, glandular disturbances, varicose veins, epilepsy, palsy, cataracts, catarrhal conditions, tooth malformation, excessive acid, stomach trouble, and other degenerative diseases; for use as an aid in lengthening life; for providing resistance to infection and epidemics; for improving the health of people suffering from a wide variety of nutritional diseases; for helping nutritionally to relieve, ease, and lessen excessive acid pains in arthritis; for increasing resistance to the causative factors of disease; and for aiding in preventing flu, such as was prevalent in the 1918 epidemic.

The complaint alleged also that the defendants had been repeatedly informed that the drugs manufactured and distributed in interstate commerce by them were misbranded; that this information had been imparted to the defendants through a number of seizure actions, as well as by opportunities afforded them to present their views in respect to alleged criminal violations as provided for in Section 305 of the Act; that there had been much correspondence and numerous interviews between the defendants and officials of the Food and Drug Administration involving the labeling of the drugs; that at the inception of the defendants' operations, Mineralized Foods, Inc., through its president, Nathan S. West, sought to promote the sales of the drugs in question through false and misleading representations placed on the labels of the drugs; that as the result of regulatory action these representations were removed from the labels and incorporated in booklets accompanying the articles when shipped in interstate commerce; and that continued seizures of the articles misbranded in such manner had resulted in the defendants turning to the promotion of sales of the drugs by means of the stated oral advertising and the distribution of the above-mentioned booklet and other media.

Prayer of Complaint: That the defendants be perpetually enjoined from commission of the acts complained of.

Disposition: March 15, 1948. The defendants having filed an answer denying the allegations of the complaint, but having consented subsequently to the entry of a decree, the court issued an order enjoining the defendants from directly or indirectly introducing or delivering for introduction in interstate commerce, any drug the labeling of which omitted in whole or in part the disease or condition and the directions for use for the disease or condition for which the drug was intended to be used, recommended, or suggested in the oral or written advertising disseminated or sponsored by or on behalf of the defendants, or any drug which was otherwise misbranded within the meaning of Section 502 (f) (1).

2354. Action to enjoin and restrain the interstate shipment of a drug known as "Dr. Haller's Prescription 5,000" or "Dr. Haller's Prescription 2,000," or "Rx 2,000" or "Rx 5,000." U. S. v. Walter Kurt Max Hassenstein (Hassenstein Co.). Consent decree granting injunction. (Inj. No. 189.)

COMPLAINT FILED: On or about March 10, 1948, Southern District of California, against Walter Kurt Max Hassenstein, trading as the Hassenstein Co., Hollywood, Calif.

NATURE OF CHARGE: That the defendant was engaged in the interstate distribution of a drug preparation designated as "Rx 5,000"; that prior to the time the defendant began trading as the Hassenstein Co., he had under various trade names and styles, and as the responsible official of Lewyn Drug, Inc., of Hollywood, Calif., caused to be introduced and delivered for introduction into interstate commerce the same drug under the designations "Dr. Haller's Prescription 2,000," "Dr. Haller's Prescription 5,000," "Rx 5,000," or "Rx 2,000," under representations that the preparation was an efficacious treatment for delayed menstruation, and that its use would have no ill effects; that such representations were false, in that the use of the preparation did not constitute an efficacious treatment for delayed menstruation and might be dangerous to health if used in the presence of heart trouble, kidney disease, or high blood pressure, or if used in cases of impending accidental termination of pregnancy or advanced stages of pregnancy; that by reason of the defendant's unlawful activities a preliminary injunction was issued on April 7, 1939, and a cease and desist order was issued by the Federal Trade Commission on June 6, 1939, against Lewyn Drug, Inc.; that a post office fraud order was issued on February 27, 1939, against Lewyn Drug, Inc., and others; and that the defendant was convicted on December 1, 1941, upon charges of using and causing the use of the mails to defraud.

The complaint alleged further that the defendant was at the time the complaint was filed, trading as the Hassenstein Company and had been and was causing to be introduced and delivered for introduction into interstate commerce the same drug under the designation "Rx 5,000"; that the boxes containing the drug were labeled, in part: "Rx 5000 White Tablets Each Contains: Extract Cotton Root Bark * * * 1 grain, Extract Black Helebore 1 grain, Ergotin 1 grain, Aloes 1 grain, Iron Sulphate 1 grain, Oily Pennyroyal ½ minim * * * Oil Savin * * * ¼ minim 6 Capsules, Each Contains: Ergotin 1 grain, Oil Savin * * * ½ minim, Aloin ⅛ grain, Apiol Green 3 minims 3 Ampuls, Each Contains: Solution Posterior Pituitary U. S. P. ½ cc Chlorobutanol 0.5% * * * 3 cotton rolls, 1 glass rod, 1 file"; and that enclosed in each of the boxes was a certain circular headed "Rx 5000 Important," which contained, among others, the following statement, "Ampules should not be used in cases of nephritis, myocarditis, arteriosclerosis."

The complaint alleged further that the article so labeled, and introduced, and delivered for introduction into interstate commerce by the defendant was misbranded as follows:

Section 502 (f) (1), the labeling failed to bear adequate directions for use by reason of the failure of the labeling to state any condition, disease, or function for which the preparation was to be used, and for which it would be effective when used in accordance with the dosage, methods, and duration of administration set forth in the labeling. Section 502 (f) (2), the labeling failed to bear adequate warnings against use in those pathological conditions where its use may be dangerous to health, in such manner and form as are necessary for the protection of users, since it contained a solution of posterior pituitary, and the statement in the labeling "should not be used in cases of nephritis, myocarditis and arteriosclerosis" was not adequate to warn against use of the product in kidney disease, heart disease, and hardening of the arteries; and since the use of a product containing posterior pituitary may be dangerous to the health of persons with high blood pressure, and the labeling of the product bore no warning against use by persons with high blood pressure.

The complaint alleged also that the product was intended for use in the treatment of delayed menstruation, but that labeling statements representing or suggesting it for such use would be false and misleading, since it was not efficacious in the cure, mitigation, treatment, or prevention of delayed menstruation; that any labeling statements representing or suggesting the use of the preparation as a drug would be false and misleading, since the preparation was without value in the cure, mitigation, treatment, or prevention of disease, or to affect any function of the human body except to induce severe purgation; and that its prime physiological effect was to induce labor when administered near term in the pregnant female, in which case it was

dangerous to health when used in the amounts, and with the frequency and duration directed, because the posterior pituitary ingredient would cause spastic contractions of the uterus with possible rupture and consequent death to the mother and injury or death to the child.

PRAYER OF COMPLAINT: That the defendant be perpetually enjoined from shipping in interstate commerce in violation of Section 301 (a), the said drug preparation under the above-mentioned designations, or under any other designation, which would be misbranded within the meaning of Sections 502 (a), or (f) (1) and (2).

DISPOSITION: June 7, 1948. The defendant having consented to the entry of a decree, judgment was entered perpetually enjoining the defendant from directly or indirectly causing to be introduced or delivered for introduction in interstate commerce, in violation of Section 301 (a), the drug preparation under the designation of "Dr. Haller's Prescription 2,000," "Dr. Haller's Prescription 5,000," "Rx 5,000," or "Rx 2,000," or under any other designation, which would be misbranded within the meaning of Sections 502 (a), or (f) (1) and (2).

2355. Alleged misbranding of Rx 5,000. U. S. v. Walter Kurt Max Hassenstein (Hassenstein Co.). Motion granted for dismissal of information. (F. D. C. No. 20946. Sample Nos. 15984–H, 47152–H.)

INFORMATION FILED: November 13, 1946, Southern District of California, against Walter Kurt Max Hassenstein, trading as the Hassenstein Co., Hollywood, Calif.

ALLEGED SHIPMENT: On or about July 25, 1945, and March 28, 1946, from the State of California into the States of Colorado and Illinois.

PRODUCT: Examination disclosed that each package of the product consisted of 22 white tablets, 6 capsules, and 3 ampoules, together with 3 cotton rolls, 1 file, and 1 glass rod. Analyses indicated that the products contained the ingredients declared on the label, i. e., (tablets) extract of cotton root bark, extract of black hellebore, ergotin, aloes, iron sulfate, oil of pennyroyal, and oil of savin; (capsules) ergotin, oil of savin, aloin, and apiol green; and (ampoules) solution of posterior pituitary and chlorobutanol.

NATURE OF CHARGE: Misbranding, Section 502 (f) (1), the labeling of the article failed to bear adequate directions for use, since the directions contained in the labeling were not adequate, because the labeling failed to reveal the reason for using the article. Further misbranding, Section 502 (f) (2), the labeling of the article failed to bear adequate warnings against use in those pathological conditions where its use may be dangerous to health, in such manner and form as are necessary for the protection of users, since the article contained a solution of posterior pituitary, and the statement in the labeling "should not be used in cases of nephritis, myocarditis and arteriosclerosis" was not adequate to warn against use of the article in kidney disease, heart disease, and hardening of the arteries; and since the labeling of the article bore no warning against use by persons with high blood pressure.

DISPOSITION: May 8, 1947. A motion for dismissal of the information was filed on behalf of the defendant, and after consideration of the briefs and arguments of counsel, the court granted the motion and handed down the following decision:

HALL, *District Judge:* "The statement on the label 'IMPORTANT To be used as directed by physician,' is in my judgment an 'adequate direction' for the use of the product. It is not to be used at all unless a physician directs it. To put more on the label would be to suggest it could be used without the direction of a physician which would be more apt to be false and misleading than the simple statement as used.

"The words 'nephritis, myocarditis, and arteriosclerosis' are dictionary words which are commonly understood to mean certain types of kidney, heart or arterial diseases. The warning that the product should not be used in such cases appearing under the word 'IMPORTANT' together with the statement, 'To be used as directed by physician' is an 'adequate warning' sufficient to comply with the statute as to all except children, and is not false or misleading.

"As to the 'adequate warning against its use by children' I do not know how a more adequate warning could be given on a label than the statement 'Not to be used by children.'

"The motion to dismiss is granted."

2356. Misbranding of Sev-A-Jay capsules, sodium amytal capsules, and seconal sodium capsules. U. S. v. Harry Cavassa (Peninsula Drug Co.). Motion for dismissal of information denied. Plea of not guilty; verdict of guilty. Fine, $1,200. Judgment affirmed on appeal to circuit court of appeals. (F. D. C. No. 17867. Sample Nos. 73528–F, 29075–H, 29564–H, 29570–H, 29576–H, 29683–H.)

INFORMATION FILED: June 19, 1946, Northern District of California, against Harry Cavassa, trading as the Peninsula Drug Co., San Francisco, Calif.

INTERSTATE SHIPMENT: Between the approximate dates of October 27, 1943, and May 16, 1945, from Detroit, Mich., and Indianapolis, Ind., of 1 lot of *Sev-A-Jay capsules*, 1 lot of *sodium amytal capsules*, and 4 lots of *seconal sodium capsules*.

PRODUCT: The *Sev-A-Jay capsules*, *sodium amytal capsules*, and two lots of the *seconal sodium capsules* had been made for use exclusively by or on the prescription of a physician, and the labels bore the statement "Caution—To be used only by or on the prescription of a physician." As a result, the drugs were not required to comply with Section 502 (f) (1), which requires that adequate directions for use appear in the labeling.

LABEL, WHEN SHIPPED: "Sev-A-Jay * * * each capsule contains: Aloin 1/8 gr. Apiol 5 Min. Ergot 4 grs."; "Pulvules Sodium Amytal 1 Gr. (0.065 Gm.)"; and "Pulvules Seconal Sodium 1½ Grains (0.1 Gm.)."

NATURE OF CHARGE: *Sev-A-Jay capsules*, *sodium amytal capsules*, and two lots of *seconal sodium capsules*. On or about August 29, 1944, and March 16 and 29 and May 16, 1945, while the drugs were being held for sale after shipment in interstate commerce, the defendant caused them to be sold, delivering them to the purchasers in the bottles labeled as indicated above, without a physician's prescription. The sale of these drugs by the defendant caused the exemption to expire and resulted in the misbranding of the drugs in violation of Section 502 (f) (1), since the bottles bore no labeling containing directions for use.

Seconal sodium capsules (2 lots). On or about March 27 and April 13, 1945, the defendant caused to be repacked a number of the capsules into an envelope labeled "Seconal" and into an unlabeled vial and sold them without a prescription. The acts of the defendant resulted in the drug being misbranded in violation of Section 502 (f) (1), since the envelope and the vial bore no labeling containing directions for use; and, Section 502 (f) (2), since the envelope and vial bore no labeling containing warnings against use in those pathological conditions and by children where its use may be dangerous to health and against unsafe dosage and methods and duration of administration.

DISPOSITION: The defendant filed a motion to dismiss the information on the grounds (1) that the information did not state facts sufficient as a matter of law to constitute any offense against the laws of the United States; (2) that the court did not have jurisdiction of the subject matter involved; (3) that the acts of the defendant complained of were in local and intrastate commerce and not in interstate commerce; (4) that the defendant's acts were beyond the power of Congress to regulate and punish; (5) that the applicable provisions of the Food, Drug, and Cosmetic Act involved in each count were unconstitutional as beyond the scope and power of congressional legislation under the commerce clause of the Constitution.

On October 4, 1946, after argument of counsel, the court denied the motion to dismiss. On October 14, 1946, the defendant entered a plea of not guilty. The case came on for trial before the court without a jury, and after consideration of the evidence the court, on November 7, 1946, found the defendant guilty and imposed a fine of $200 on each of the 6 counts of the information. Notice of appeal was thereafter filed on behalf of the defendant with the United States Circuit Court of Appeals for the Ninth Circuit. On February 4, 1948, a decision was handed down by that court, affirming the judgment of conviction on the authority of U. S. v. Sullivan, 68 S. Ct. 331.

2357. Misbranding of phenobarbital tablets. U. S. v. Reginald J. Price, manager of Shell Lake Drug Co. Plea of guilty. Defendant fined $75, given sentence of 6 months in jail, which was suspended, and placed on probation for 1 year. (F. D. C. No. 23209. Sample Nos. 51712–H, 51807–H, 51818–H.)

INFORMATION FILED: June 26, 1947, Western District of Wisconsin, against Reginald J. Price, manager of the Shell Lake Drug Co., Shell Lake, Wis.

INTERSTATE SHIPMENT: On or about February 1, 1945, from St. Louis, Mo., to Shell Lake, Wis., of quantities of *phenobarbital tablets*.

LABEL, WHEN SHIPPED: "Tablets Phenobarbital U. S. P. XII 1½ Grains."

ALLEGED VIOLATION: On or about July 13, 14, and 31, 1946, while the tablets were being held for sale after shipment in interstate commerce, the defendant caused a number of tablets to be removed from the bottle in which they had been shipped, repacked the tablets into envelopes, and sold them to various persons without a prescription, which acts of the defendant resulted in the tablets being misbranded. A portion of the repackaged tablets were labeled "Use as directed," and the remainder of such tablets were labeled "Phenobarbitals 1½ gr. Use as directed."

NATURE OF CHARGE: Misbranding, Section 502 (d), the tablets were drugs for use by man and contained a chemical derivative of barbituric acid, which derivative had been found by the Administrator of the Federal Security Agency, after investigation, to be, and by regulations designated as, habit-forming; and the labels of the repackaged tablets failed to bear the name and quantity or proportion of such derivative and in juxtaposition therewith the statement "Warning—May be habit forming." Further misbranding, Section 502 (f) (1), the envelopes containing the repackaged tablets bore no labeling containing directions for use; and, Section 502 (f) (2), the envelopes containing the repackaged tablets bore no labeling containing warnings against use in those pathological conditions and by children where their use may be dangerous to health, and against unsafe dosage and duration of administration.

DISPOSITION: June 2, 1948. A plea of guilty having been entered, the court imposed a fine of $75 and a sentence of 6 months in jail, which sentence was suspended, and placed the defendant on probation for 1 year.

2358. Misbranding of Red Rooster Pills and Gen Tablets. U. S. v. Victor Edison Perry, The Vim Co., and The Vim Vitamin Co.). Plea of guilty. Sentence of 60 days in jail. (F. D. C. No. 23623. Sample Nos. 68823–H, 69503–H, 69955–H, 69956–H, 70159–H, 70160–H.)

INDICTMENT RETURNED: On December 3, 1947, Northern District of Illinois, against Victor Edison Perry, trading as the Vim Co. and the Vim Vitamin Co., Chicago, Ill.

ALLEGED SHIPMENT: Between the approximate dates of March 31 and July 5, 1947, from the State of Illinois into the States of Michigan, Wisconsin, and Indiana.

LABEL, IN PART: "Red Rooster Famous Red Pills The Pep Company Windsor, Ont., Canada. Each pill contains the following active ingredients: Strychnine Sulfate 1–50 gr., Yohimbine Hydrochloride 1–12 gr., Zinc Phosphidel 1–10 gr.; and the following inert ingredients: Orchic Substance 1–10 gr., Avenin 1 gr., P. E. Damiana 1–20 gr."; or "Gen * * * Tablets * * * Each tablet contains: 1 gr. Acetanilid, with Aloin, Ext. Cascara Sagrada, Podophyllin and Capsicum."

NATURE OF CHARGE: *Red Rooster Pills.* Misbranding, Section 502 (a), certain statements and pictures on the label of the article and in circulars entitled "No, You are . . . Not Too Old For Romance," which were mailed to the consignees in certain shipments separate from the shipment of the drug, and in circulars entitled "Perry's World Famous Red Rooster Pills" and "Vim Nature Health Products," which were enclosed with various portions of the drug, were false and misleading. These statements and pictures represented and suggested that the article was famous and would work wonders for man and wife; that it would stimulate sexual desire, give new pep, vim, vigor, and vitality to users, and keep one young; and that the article never failed to give pep for man and wife. The article was not famous, and it would not be effective for the purposes and would not fulfill the promises of benefit stated and implied.

Gen Tablets. Misbranding, Section 502 (a), certain statements on the card entitled "World's Best Blood Tonic Gen-Sen For Clean Pure Blood," which was enclosed in the package containing the article, were false and misleading. These statements represented and suggested that the article would be effective as the world's best tonic for clean pure blood, and that it would be effective to stop dizzy headache, to clean and purify the excess acid in blood, to make one feel 10 years younger, to give relief for high or low blood pressure, to build one, to give relief from rheumatism, getting up nights, arthritis, diabetes, lumbago, neuritis, backache, indigestion, lazy liver, neuralgia, nervousness, biliousness, gas, swollen feet, weak kidneys, weak bladder, colds, sinus, coughs, flu, and fever. The article would not be effective for the purposes and would not fulfill the promises of benefit stated and implied. Further misbranding

(both shipments), Section 502 (f) (1), the labeling failed to bear adequate directions for use in the conditions recommended and suggested in the advertising cards "World's Best Blood Tonic Gen-Sen For Clean Pure Blood," which were delivered to the consignee of one shipment and which were shipped with the other shipment.

DISPOSITION: May 20, 1948. A plea of guilty having been entered, the court imposed a sentence of 60 days in jail.

2359. Misbranding of Sanger Special Formula Single Strength Prescription and Sanger Special Formula Double Strength Prescription. U. S. v. Carl J. Greenblatt (G & W Laboratories). Plea of guilty. Fine of $500 and jail sentence of 3 months; jail sentence suspended and defendant placed on probation for 1 year. (F. D. C. No. 23261. Sample Nos. 91126–H, 91127–H.)

INFORMATION FILED: December 5, 1947, District of New Jersey, against Carl J. Greenblatt, trading as G & W Laboratories, Jersey City, N. J.

ALLEGED SHIPMENT: On or about February 14, 1947, from the State of New Jersey into the State of New York.

PRODUCT: Examination showed that both products were substantially of the same composition. Brown pills consisting essentially of ferrous sulfate, aloes, and oil of tansy, and white pills consisting essentially of jalap, aloes, calomel, and plant extractives, and both with a calcium carbonate sugar coating, were contained in separate envelopes in a box.

NATURE OF CHARGE: Misbranding, Section 502 (a), the statements in the leaflet headed "Recommended Instructions" enclosed in the boxes, i. e., "Female Tablets * * * prepared as an aid to delayed menstruation caused by exposure to inclement weather and cold * * * should be continued until desired relief results * * * female * * * prescription," were false and misleading, since they represented and suggested that the article would be efficacious to bring about menstruation when menstruation was delayed, whereas they would not be efficacious for such purposes.

Further misbranding, Section 502 (e) (2), the articles were not designated solely by names recognized in an official compendium and were fabricated from two or more ingredients; they contained a preparation of mercury, calomel; and their labels failed to bear the common or usual name of each active ingredient, including the name, quantity, or proportion of the preparation of mercury. Section 502 (f) (2), the articles were a laxative and their labelings failed to warn that they should not be used when abdominal pain, nausea, vomiting, or other symptoms of appendicitis were present, and that frequent or continued use of the articles might result in dependence on laxatives to move the bowels; and, Section 502 (b) (2), the labels of the articles bore no statement of the quantity of the contents.

DISPOSITION: March 24, 1948. A plea of guilty having been entered, the defendant was fined $500, was given a suspended sentence of 3 months in jail, and was placed on probation for 1 year.

2360. Misbranding of Jaxon Periodic Medicine. U. S. v. Milton L. Lieberman (Jaxon Products Co.). Plea of guilty. Fine, $100 and costs. (F. D. C. No. 23255. Sample No. 15769–H.)

INFORMATION FILED: January 19, 1948, Northern District of Illinois, against Milton L. Lieberman, trading as the Jaxon Products Co., Chicago, Ill.

ALLEGED SHIPMENT: On or about November 4, 1946, from the State of Illinois into the State of Wisconsin.

PRODUCT: Analysis disclosed that the product consisted of black-coated tablets containing an alkaloid, an emodin bearing drug, asafetida, and iron.

NATURE OF CHARGE: Misbranding, Section 502 (a), the statement on the box "Periodic Medicine," and certain statements in leaflets entitled "Directions" and "Price List and Order Blank" enclosed in the box, were false and misleading, since they represented and suggested that the article would be of value for use during menstrual periods; that it would be efficacious in the treatment of amenorrhea (unnatural suppression of menstruation), dysmenorrhea (difficult or painful menstruation), oligomenorrhea (scanty, suppressed menstruation), menotasis (menstrual pain preceding menstruation and resultant transient nervousness and irritability), and functional disorders due to colds, worry, fear (pseudo-pregnancy); and that it would be efficacious in the treatment of functional distress due to colds, worry, fear, and those conditions implied by the abbreviation "etc." The article would not be of value, and it would not be efficacious for the purposes represented.

Further misbranding, Section 502 (b) (2), the label of the article failed to bear an accurate statement of the quantity of contents, since the label on the container of the article bore no statement of the quantity of the contents; and, Section 502 (f) (2), it failed to bear such adequate warnings against use in those pathological conditions where its use may be dangerous to health, in that it contained yohimbine hydrochloride and the use of a product containing yohimbine hydrochloride may be dangerous to the health of persons with heart disease, high blood pressure, and kidney disease, and the labeling of the article bore no warning against use by persons with such diseases and conditions.

DISPOSITION: February 17, 1948. A plea of guilty having been entered, the court imposed a fine of $100 and costs.

2361. Misbranding of Bra'zil's Liquid Compound and Bra'zil's Powder Compound. U. S. v. Yancy T. Shehane (Bra'zil Medicine Co.). Plea of nolo contendere. Fine, $200. (F. D. C. No. 17875. Sample Nos. 19229–H, 19230–H, 22166–H, 22167–H.)

INFORMATION FILED: July 29, 1946, Western District of Arkansas, against Yancy T. Shehane, trading as the Bra'zil Medicine Co., Arkadelphia, Ark.

ALLEGED SHIPMENT: On or about April 16 and May 30, 1945, from the State of Arkansas into the States of Minnesota and Illinois.

PRODUCT: Analysis disclosed that the *Bra'zil's Liquid Compound* was a dark brown liquid containing chiefly salicylates and iodides of sodium and potassium, water, alcohol, guaiacol, and plant extractive material including colchicine and strychnine bearing drugs; and that the *Bra'zil's Powder Compound* was a white powder containing sodium bicarbonate and magnesium sulfate (epsom salt).

NATURE OF CHARGE: Misbranding Section 502 (a), certain statements in a leaflet entitled "Arthritis and Rheumatic Sufferers," which was enclosed with the articles, were false and misleading, since they represented and suggested that the articles when taken in conjunction with each other would be an effective treatment for arthritis, neuritis, sciatica, inflammatory rheumatism, soreness, swelling, and stiff tendencies in the joints, whereas the articles when taken alone or in conjunction with each other would not be an effective treatment for such conditions.

Further misbranding, Section 502 (e) (2), the articles were not designated solely by a name recognized in an official compendium, and they were fabricated from two or more ingredients; the label of the liquid compound failed to bear a statement of the quantity, kind, and proportion of alcohol, and a statement of the quantity and proportion of strychnine in the article; and the label of the powder compound failed to bear the common or usual name of each active ingredient, i. e., epsom salt. Section 502 (f) (1), the labeling of the powder compound failed to bear adequate directions for use, since the directions suggested continued use of the article, whereas the article was a laxative and should not be used continuously.

Further misbranding, Section 502 (f) (2), the labeling of the articles failed to bear adequate warnings against use in those pathological conditions or by children where their use may be dangerous to health, or against unsafe dosage or methods or duration of administration, in such manner and form as are necessary for the protection of users. The liquid compound contained potassium iodide, strychnine, and colchicum seed, and its labeling failed to bear a warning that a drug containing potassium iodide should not be used by persons with lung disease, chronic cough, or goiter (thyroid disease), except upon the advice of a physician; that a drug containing strychnine should not be used by children; that frequent and continued use of a drug containing colchicum seed and strychnine should be avoided; that the use by elderly persons of a drug containing strychnine is unsafe; and that use of a drug containing potassium iodide should be discontinued if a skin rash appears. The powder compound was a laxative, and its labeling failed to bear warnings that the article should not be used in the presence of abdominal pain (stomach ache, cramps, and colic), nausea, vomiting (stomach sickness), or other symptoms of appendicitis, and that frequent and continued use of the article might result in dependence upon laxatives to move the bowels.

DISPOSITION: April 25, 1947. A plea of nolo contendere having been entered, the court imposed a fine of $200.

2362. Misbranding of Lanteen cup diaphragm and jelly set. U. S. v. 159 Dozen Packages * * *. (F. D. C. No. 20251. Sample No. 29667–H.)

LIBEL FILED: June 20, 1946, Northern District of California; amended libel filed April 1, 1947.

ALLEGED SHIPMENT: On or about April 18 and 19, 1946, by Lanteen Medical Laboratories, Inc., from Chicago, Ill.

PRODUCT: 159 dozen articles of device at San Francisco, Calif., which were labeled in part "Lanteen Cup Diaphragm and Jelly Set." Each set consisted of a rubber diaphragm, two tubes of jelly, and a blooklet entitled "Directions For Marriage Hygiene."

NATURE OF CHARGE: Misbranding, Section 502 (a), the labeling of the articles was false and misleading, since it represented and suggested that the rubber diaphragm and jelly were effective in preventing conception when used as directed, whereas they were not effective for such purpose.

DISPOSITION: April 23, 1948. Lanteen Medical Laboratories, Inc., claimant, having consented to the entry of a decree, judgment of condemnation was entered. The decree made no finding on the charge under Section 502 (a), but found that the articles were misbranded in violation of Section 502 (f) (1), in that statements and designs in the booklet represented and suggested that the directions contained in the booklet were adequate and sufficient for the use of the product in preventing conception, whereas the directions for use were not adequate and sufficient for such purpose. The product was ordered released under bond to be relabeled.

DRUG ACTIONABLE BECAUSE OF CONTAMINATION WITH FILTH

2363. Adulteration of Tebsin Tablets. U. S. v. S. O. Barnes & Son and Alfred O. Barnes. Motion to strike denied. Plea of nolo contendere. Fine of $1,000 against each defendant. (F. D. C. No. 20983. Sample Nos. 31260–H, 58847–H.)

INDICTMENT RETURNED: March 12, 1947, Southern District of California, against S. O. Barnes & Son, a partnership, Gardena, Calif., and Alfred O. Barnes, a partner in the partnership, for the offense of giving a false guaranty.

ALLEGED VIOLATION: On or about January 25, 1945, the defendants caused to be given to W. B. Nisbet, trading as the W. B. Nisbet Co., of Los Angeles, California., a guaranty providing that no drug shipped or delivered by the defendants to the W. B. Nisbet Co., described in the guaranty as the "Distributor," would be misbranded within the meaning of the Federal Food, Drug, and Cosmetic Act; that the potency of the vitamin content of all merchandise furnished to the distributor was guarantied for a period of 6 months from the date of shipment or delivery to the distributor; that labels used on all merchandise furnished to the distributor were to be furnished and placed on the merchandise by the distributor; that all labels used by the distributor must conform to all rules and regulations of the Food and Drug Administration; and that the distributor would assume full responsibility for any variation from the above in respect to information added to or omitted from labels used, as required by the Food and Drug Administration, and would accept full responsibility for any charges of adulteration or misbranding that may result therefrom.

On or about February 22, 1946, the defendant caused to be delivered to W. B. Nisbet at Los Angeles, Calif., a number of tablets, and between that date and March 28, 1946, W. B. Nisbet packed the tablets into bottles bearing the label "Tebsin Tablets" and delivered them to Tebsin Sales, Inc., at Los Angeles, Calif. Between March 19 and 28, 1946, Tebsin Sales, Inc., shipped the tablets from the State of California into the State of Washington. The Tablets so guarantied, delivered, and shipped were adulterated.

NATURE OF CHARGE: Adulteration, Section 501 (a) (1), the tablets consisted in part of a filthy substance by reason of the presence of rodent hairs and rodent hair fragments; and, Section 501 (a) (2), they had been prepared, packed, and held under insanitary conditions whereby they may have become contaminated with filth.

The indictment alleged also that the defendant had given a false guaranty with respect to a food known as *Beir-Nes Tablets*, as reported in notices of judgment on foods.

DISPOSITION: The defendants moved to strike from the indictment the allegations with respect to the shipment of the product in interstate commerce,

on the grounds that the defendants could not be criminally liable for the acts of third parties or for an act in which the defendants did not participate. The defendants' motion was denied by the court on April 21, 1947. Thereafter, a plea of nolo contendere was entered on behalf of the defendants, and on September 15, 1947, the court imposed a fine of $1,000 against each defendant.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF DEVIATION FROM OFFICIAL OR OWN STANDARDS

2364. Adulteration and misbranding of Met-Estrin. U. S. v. Metropolitan Laboratories, Inc., and Rudolph N. Price. Pleas of guilty. Fine, $500 against defendants jointly. (F. D. C. No. 17856. Sample Nos. 6027–H, 6028–H, 16540–H.)

INFORMATION FILED: January 21, 1948, Southern District of New York, against the Metropolitan Laboratories, Inc., New York, N. Y., and Rudolph N. Price, president of the corporation.

ALLEGED SHIPMENT: Between the approximate dates of January 23 and April 10, 1945, from the State of New York into the States of New Jersey and Illinois.

LABEL, IN PART: "Metro Met-Estrin (Estrogenic Substance)."

NATURE OF CHARGE: Adulteration, Section 501 (d), an oil solution of estradiol with insignificant amounts of estrone or other ketosteroids had been substituted in whole or in part for a mixture of natural estrogens derived from pregnancy urine, which the article purported and was represented to be.

Misbranding, Section 502 (e) (2), the article was not designated solely by a name recognized in an official compendium and was fabricated from two or more ingredients, and its label failed to bear the common or usual name of each active ingredient, since the label designation "Estrogenic Substance" is not the specific name of any particular substance but is a generic name for a class of substances.

DISPOSITION: April 6, 1948. Pleas of guilty having been entered, the court imposed a fine of $500 against the defendants jointly.

2365. Adulteration and misbranding of Thionicavin No. 2. U. S. v. Chicago Pharmacal Co. and Chester H. Taylor and William B. Taylor, Jr. Pleas of guilty. Fine, $1,000. (F. D. C. No. 23217. Sample Nos. 57491–H, 64989–H.)

INFORMATION FILED: September 9, 1947, Northern District of Illinois, against the Chicago Pharmacal Co., a corporation, Chicago, Ill., and Chester H. Taylor, president, and William B. Taylor, Jr., secretary and treasurer, of the corporation.

ALLEGED SHIPMENT: On or about September 9 and 10, 1946, from the State of Illinois into the States of Vermont and New York.

LABEL, IN PART: "Sterile Solution No. 54B Thionicavin No. 2 For Intramuscular or Intravenous Use Multiple Dose Package."

NATURE OF CHARGE: Adulteration, Section 501 (d), a product containing estradiol in sesame oil had been substituted for a product containing thiamine hydrochloride, riboflavin, pyridoxine hydrochloride, nicotinamide, urea, and redistilled water, which the article purported and was represented to be.

Misbranding, Section 502 (a), the labels of the article represented and suggested that the article was suitable for intravenous use; that each cubic centimeter of the article contained 100 milligrams of thiamine hydrochloride, 5 milligrams of riboflavin, 2.5 milligrams of pyridoxine hydrochloride, 100 milligrams of nicotinamide, 100 milligrams of urea, 10 milligrams of benzyl alcohol, and redistilled water sufficient to make one cubic centimeter; that the article was suitable for use in correcting and preventing beriberi, pellagra, and anorexia, in securing optimal growth of infants and children, in impaired lactation, in pernicious vomiting of pregnancy, and in deficiencies of the B vitamins; and that one cubic centimeter of the article contained about fifty times the thiamine, two times the riboflavin, and five and one-half times the nicotinamide daily optimum adult intake. The article consisted of estradiol in sesame oil and was not suitable for intravenous use; it did not contain thiamine hydrochloride, riboflavin, pyridoxine hydrochloride, nicotinamide, urea, and redistilled water; it was not suitable for use for the purposes represented; and it would not furnish any thiamine, riboflavin, and nicotinamide.

DISPOSITION: October 7, 1947. Pleas of guilty having been entered on behalf of all defendants, the court imposed a fine of $1,000 and costs and ordered that the fine be paid by the corporation.

2366. Adulteration of aminophylline and misbranding of thiamine hydrochloride. U. S. v. Medicinals, Inc. Plea of guilty. Fine, $600. (F. D. C. No. 23246. Sample Nos. 40106–H, 65268–H.)

INFORMATION FILED: January 20, 1948, Eastern District of New York, against Medicinals, Inc., Richmond Hill, N. Y.

ALLEGED SHIPMENT: On or about September 23 and 25, 1946, from the State of New York into the States of Tennessee and Pennsylvania.

LABEL, IN PART: "Aminophylline U. S. P.," or "Thiamine Hydrochloride * * * Distributed by Physicians' Drug & Supply Co. Philadelphia, Pa."

NATURE OF CHARGE: *Aminophylline.* Adulteration, Section 501 (b), the article purported to be and was represented as "Theophylline Ethylenediamine Injection [Aminophylline Ampuls]," a drug the name of which is recognized in the United States Pharmacopoeia, and its strength differed from, and its quality and purity fell below, the official standard; and its difference in strength, quality, and purity from the standard was not plainly stated, or stated at all, on its label. The standard provides that the drug should contain an amount of anhydrous theophylline equivalent to not less than 73 percent and not more than 83 percent of the labeled amount of theophylline ethylenediamine, and that injections which are solutions of soluble medicaments must be free of undissolved material which can be detected readily when tested in accordance with the method described in the United States Pharmacopoeia. Some ampoules of the article contained an amount of anhydrous theophylline equivalent to less than 73 percent, and other ampoules contained an amount of anhydrous theophylline equivalent to more than 83 percent of the labeled amount of theophylline ethylenediamine. Further, the article contained undissolved material which could be readily detected when tested in accordance with the prescribed method.

Thiamine hydrochloride. Misbranding, Section 502 (a), the label statement "Thiamine Hydrochloride 200 mg. per cc. (Equiv. to 66,000 units of Vitamin B_1 per cc.)" was false and misleading, since the article contained less than that amount of thiamine hydrochloride per cubic centimeter.

DISPOSITION: February 11, 1948. A plea of guilty having been entered, the court imposed a fine of $600.

2367. Adulteration of thiamine hydrochloride. U. S. v. 72 Vials * * *. (F. D. C. No. 23709. Sample No. 1001–K.)

LIBEL FILED: September 25, 1947, Southern District of Florida.

ALLEGED SHIPMENT: On or about August 13, 1947, by the Gotham Pharmaceutical Co., Inc., from Brooklyn, N. Y.

PRODUCT: 72 30-cc. size vials of thiamine hydrochloride at Miami, Fla.

LABEL, IN PART: "Thiamine Hydrochloride * * * Intramuscular-Intravenous."

NATURE OF CHARGE: Adulteration, Section 501 (b), the article purported to be and was represented as "Thiamine Hydrochloride Injection," a drug the name of which is recognized in the United States Pharmacopoeia, and its quality and purity fell below the official standard, since it was contaminated with undissolved material.

DISPOSITION: July 28, 1948. Default decree of forfeiture and destruction.

2368. Adulteration of thiamine hydrochloride. U. S. v. 38 Vials * * *. (F. D. C. No. 23708. Sample No. 12901–K.)

LIBEL FILED: September 17, 1947, Eastern District of Pennsylvania.

ALLEGED SHIPMENT: On or about August 21, 1947, by the Gotham Pharmaceutical Co., Inc., from Brooklyn, N. Y.

PRODUCT: 38 30-cc. vials of *thiamine hydrochloride* at Philadelphia, Pa.

LABEL, IN PART: "Thiamine Hydrochloride * * * Intramuscular-Intravenous."

NATURE OF CHARGE: Adulteration, Section 501 (b), the article purported to be and was represented as "Thiamine Hydrochloride Injection," a drug the name of which is recognized in the United States Pharmacopoeia, and its quality and purity fell below the official standard, since it was contaminated with undissolved material.

DISPOSITION: December 1, 1947. Default decree of condemnation and destruction.

2369. Adulteration of sodium chloride isotonic solution. U. S. v. 141 Vials * * * (and 1 other seizure action). (F. D. C. Nos. 23399, 23737. Sample Nos. 68469–H, 83357–H.)

LIBELS FILED: On or about August 8 and September 10, 1947, Southern District of Ohio and Western District of Missouri.

ALLEGED SHIPMENT: On or about March 14, June 6, and July 31, 1947, by the Pitman-Moore Co., from Indianapolis, Ind.

PRODUCT: 141 20-cc. vials and 30 250-cc. bottles of *sodium chloride isotonic solution* at Kansas City, Mo., and Columbus, Ohio, respectively.

NATURE OF CHARGE: Adulteration, Section 501 (b), the article purported to be and was represented as "Sterile Isotonic Sodium Chloride Solution for Parenteral Use," a drug the name of which is recognized in the United States Pharmacopoeia, and the quality and purity of the article fell below the official standard, since it was contaminated with undissolved material.

DISPOSITION: August 26 and November 7, 1947. Default decrees of destruction.

2370. Adulteration of sodium iodide and sodium salicylate with colchicine. U. S. v. 50 Ampoules * * *. (F. D. C. No. 23747. Sample No. 71426–H.)

LIBEL FILED: September 10, 1947, Southern District of California.

ALLEGED SHIPMENT: On or about July 25, 1947, by Bristol Laboratories, Inc., from Syracuse, N. Y.

PRODUCT: 15 20-cc. size ampoules of *sodium iodide and sodium salicylate with colchicine* at Los Angeles, Calif.

NATURE OF CHARGE: Adulteration, Section 501 (b), the article purported to be and was represented as "Sodium Salicylate and Iodide with Colchicine Ampuls," a drug the name of which is recognized in the National Formulary, and its quality and purity fell below the official standard, since it was contaminated with undissolved material.

DISPOSITION: October 23, 1947. Default decree of condemnation and destruction.

2371. Adulteration of water for injection. U. S. v. 138 Vials * * *. (F. D. C. No. 23697. Sample No. 54439–H.)

LIBEL FILED: On or about September 18, 1947, Northern District of Georgia.

ALLEGED SHIPMENT: On or about August 1, 1947, by Bristol Laboratories, Inc., from Syracuse, N. Y.

PRODUCT: 138 50-cc. size vials of *water for injection* at Atlanta, Ga.

NATURE OF CHARGE: Adulteration, Section 501 (b), the article purported to be and was represented as "Water for Injection," a drug the name of which is recognized in the United States Pharmacopoeia, and its quality and purity fell below the official standard, since it was contaminated with undissolved material.

DISPOSITION: November 3, 1947. Default decree of condemnation and destruction.

2372. Adulteration of Gen Tablets and misbranding of Red Rooster Pills. U. S. v. 6 Packages, etc. (and 1 other seizure action). (F. D. C. Nos. 23546, 23547. Sample Nos. 69955–H, 69956–H, 70159–H, 70160–H.)

LIBELS FILED: August 5, 1947, Eastern District of Michigan.

ALLEGED SHIPMENT: From Chicago, Ill., by Victor Edison Perry, trading as the Vim Vitamin Co. The products were shipped on or about March 31 and June 10 and 17, 1947, and a number of circulars were shipped on or about May 15, 1947.

PRODUCT: 6 packages of *Gen Tablets* and 67 cartons and 35 boxes of *Red Rooster Pills* at Detroit, Mich., together with a number of circulars entitled "No, You Are Not Too Old For Romance."

LABEL, IN PART: "Gen * * * Tablets * * * Each tablet contains: 1 gr. Acetanilid, with Aloin, Ext. Cascara Sagrada, Podophyllin and Capsicum," or "Red Rooster Famous Red Pills * * * Each pill contains the following active ingredients: Strychnine Sulfate 1–50 gr., Yohimbine Hydrochloride 1–12 gr., Zinc Phosphidel 1–10 gr."

NATURE OF CHARGE: *Gen Tablets.* Adulteration, Section 501 (c), the strength of the article differed from that which it was represented to possess, i. e., "Each tablet contains: 1 gr. Acetanilid," since each tablet contained less than one grain of acetanilid.

Red Rooster Pills. Misbranding, Section 502 (a), certain statements on the label of the article, together with a design of a rooster, were false and mis-

leading, since such statements and design implied that the article was famous and would work wonders for man and wife, and that it never failed. The article was not famous and would not work wonders for man and wife, and there is no known disease condition in which use of the article would be infallible. Further misbranding, Section 502 (a), certain statements, together with the designs of a rooster, of a rooster chasing a hen, and of an elderly man kissing a young woman, which appeared in the above-mentioned circular accompanying a portion of the article, and certain statements in a circular wrapped around the boxes containing a portion of the article, were false and misleading, since they represented and suggested that the article never failed to give pep for man and for wife; that it was world famous; and that it would stimulate sexual desire, give new pep and vigor to users, and keep one young. The article was not world famous and would not be effective for the purposes represented.

DISPOSITION: November 19, 1947. Default decree of condemnation. A portion of the *Gen Tablets* and the *Red Rooster Pills* was ordered destroyed, and the remainder of the products was ordered delivered to the Food and Drug Administration to be used for technical and exhibit purposes.

2373. Adulteration and misbranding of Large Round Worm Rx and misbranding of Korum. U. S. v. 287 Bottles, etc. (F. D. C. No. 20559. Sample Nos. 66888–H, 66889–H.)

LIBEL FILED: August 1, 1946, District of Nebraska.

ALLEGED SHIPMENT: On or about June 26, 1946, from Kansas City, Mo., to Lincoln, Nebr. The products were shipped by the I. D. Russell Co., via a common carrier, and a number of pamphlets relating to the products were personally transported by the consignee.

PRODUCT: 409 bottles of *Korum* and 80 packages of *Large Round Worm Rx* at Lincoln, Nebr., together with 400 pamphlets entitled "Russell's Poultry Medicines and Biologics." The bottles were in 1-gallon, ½-gallon, 1-quart, and 1-pint sizes, and the packages were in 7-ounce and 14-ounce sizes. Analyses disclosed that the *Korum* consisted of 90 percent water, with small amounts of sodium chlorate, potassium dichromate, saltpeter, and epsom salt; and that the *Large Round Worm Rx* consisted of nicotine sulfate 3 percent, copper and iron sulfates, and plant drugs such as areca nuts, capsicum, kamala, aniseed, and nux vomica.

NATURE OF CHARGE: *Large Round Worm Rx.* Adulteration, Section 501 (c), the strength of the article differed from that which it was represented to possess, i. e., nicotine sulfate 6 percent, since the article contained not more than 3 percent of nicotine sulfate. Misbranding, Section 502 (a), certain statements on the label of the article and in the pamphlets were false and misleading, since they represented and suggested that the article was effective as an aid in the control of large roundworms or any other species of worms which infest poultry. The article was not effective for such purposes.

Korum. Misbranding, Section 502 (a), certain statements on the label of the article and in the pamphlets were false and misleading, since they represented and suggested that the article was effective as a mild astringent for chicks, pullets, layers and breeders, turkeys, and poults, and that the article was effective in the prevention and treatment of disease conditions of poultry. The article was not effective for such purposes.

DISPOSITION: February 20, 1948. I. D. Russell Co., claimant, having withdrawn its claim and answer, and the libel being considered as confessed for default of pleading or answer, judgment of condemnation was entered. The court ordered that the product be destroyed and that the cost of the proceedings be taxed against the claimant.

2374. Action to enjoin and restrain the interstate shipment of prophylactics. U. S. v. Perfection Rubber Co., William B. Augustine, Ralph N. Turnbaugh, and M. E. Turnbaugh. Injunction granted. (Inj. No. 122.)

COMPLAINT FILED: October 19, 1945, Northern District of Ohio, against the Perfection Rubber Co., a corporation, Akron, Ohio, William B. Augustine, president, Ralph N. Turnbaugh, vice-president, and M. E. Turnbaugh, secretary and treasurer.

NATURE OF CHARGE: That the defendants since about November 1938, had been engaged and were still engaged in the business of manufacturing, purchasing, packing, distributing, and selling quantities of devices, and were causing the

introduction, and delivery for introduction, into interstate commerce of large quantities of said devices known as rubber *prophylactics;* that the said devices manufactured, purchased, packed, distributed, and sold by the defendants were recommended and purported to be sold for the prevention of venereal diseases; and that the devices were adulterated and misbranded in the following respects: Adulteration, Section 501 (c), the devices consisted of defective, imperfect, and old materials, and contained holes, defects, and other imperfections, so that their strength differed from, and their quality fell below, that which they purported and were represented to possess; and, misbranding, Section 502 (a), the statements in the labeling "Perfection Supreme Quality Prophylactics" were false and misleading.

The complaint alleged further that the defendants had shipped large quantities of devices in interstate commerce; that many of the shipments had been examined, found defective, and seized; that the methods of manufacture were primitive and inefficient; that the resulting product would be ineffective to prevent disease; that the defendants had in their possession a large supply of defective prophylactics which were adulterated and misbranded as aforesaid and which they intended to introduce, and were introducing, into interstate commerce; and that unless restrained and enjoined, they would continue such introduction and delivery into interstate commerce.

Prayer of Complaint: That a temporary restraining order be granted, followed by a preliminary injunction enjoining the defendants from the commission of the acts complained of, and that upon final hearing the preliminary injunction be made permanent.

Disposition: On November 27, 1945, a preliminary injunction was entered enjoining the defendants during the pendency of the action from commission of the acts complained of. On September 4, 1947, the defendants having admitted the allegations of the complaint and consented to the entry of a decree, the court entered a decree making the preliminary injunction permanent.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF FALSE AND MISLEADING CLAIMS

DRUGS FOR HUMAN USE*

2375. Alleged misbranding of Alberty's products. U. S. v. Ada J. Alberty (Alberty Food Products). Defendant's demurrer to information overruled. Plea of not guilty. Tried to the court. Judgment of guilty by district court, with probation for 3 years. Judgment reversed by Circuit Court of Appeals for Ninth Circuit. (F. D. C. No. 16522. Sample No. 81338–F, et al.)

Information Filed: On or about December 5, 1945, Southern District of California, against Ada J. Alberty, trading as Alberty Food Products, Hollywood, Calif. The information included 14 shipments of 14 different products of the defendant. All counts of the information were dismissed, with the exception of count 23 involving *Alberty Calcium Pantothenate Tablets.*

Alleged Shipment: The products were shipped between the approximate dates of October 18, 1943, and April 18, 1944, from the State of California into the State of Missouri. Certain printed matter which related to the article, and which had been shipped to the consignee on or about February 7, 1944, was alleged to constitute accompanying labeling. The *Alberty Calcium Pantothenate Tablets* were shipped on or about April 18, 1944.

Label, in Part: (*Alberty Calcium Pantothenate Tablets*, bottle label) "100 Tablets 10 Mg. (10,000 Micrograms) each of Calcium Pantothenate per tablet. Contains Dextrorotatory, Calcium Pantothenate, Dextrose and Vegetable Stearin."

Nature of Charge: *Alberty Calcium Pantothenate Tablets.* Misbranding, Section 502 (a), certain statements in leaflets entitled "So it's You again, is it?" shipped on or about February 7, 1944, were alleged to be false and misleading, in that they represented and suggested that the article would be efficacious to restore color to gray hair and to prevent hair from turning gray, whereas the article would not be efficacious for such purposes.

The information alleged also that the other products shipped by the defendant, as stated above, were misbranded because of false and misleading statements contained in the literature shipped on February 7, 1944, and that in some instances they were misbranded further with respect to their labels.

*See also Nos. 2352, 2354, 2358–2362, 2365, 2366, 2372, 2374.

DISPOSITION: On or about January 21, 1946, the defendant entered a plea of not guilty and filed a demurrer to the information. The court overruled the demurrer on February 11, 1946. Thereafter, the case proceeded to trial before the court on an agreed stipulation of facts covering count 23, relating to the *Alberty Calcium Pantothenate Tablets*, and on or about May 20, 1946, the court handed down the following opinion:

HARRISON, *District Judge*: "This is a criminal case wherein the defendant is charged in twenty-three (23) counts with a violation of the Federal Food, Drug and Cosmetic Act (Title 21, U. S. C., Sec. 301 et seq.). All counts, with the exception of Count XXIII, have been dismissed, and the case has been submitted to me on an agreed stipulation of facts, jury trial having been waived by both parties.

"All the allegations of Count XXIII are admitted, except that the defendant denies the offending circular accompanied the drug in interstate commerce within the definition of 'labeling' under the provisions of 21 U. S. C. A., Sec. 321 (m):

Sec. 321 (m)—The term "labeling" means all labels and other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article.

"The stipulation of facts discloses that the leaflets were shipped on February 7, 1944, while the drugs were not shipped until April 25, 1944. Thus there was a lapse of seventy-one (71) days between the shipping of the offending circulars and the drug. Both were shipped in interstate commerce, had a common destination, and were displayed together.

"Thus the sole issue is whether the drug and leaflets accompanied each other within the purview of the Act. Stating the issue differently, can the salutary objectives of the Act be circumvented by permitting a lapse of time to exist between the shipment of the drugs and offending leaflets from a common source to a common destination? I think not.

"I have been able to find but three cases that may be deemed as precedents. The first case is one from our own circuit, to-wit:—UNITED STATES v. RESEARCH LABORATORIES, IND., 126 F (2) 42, 45, wherein the Court stated:

The libel does not state, nor is it material, whether the packages and circulars did or did not travel in the same crate, carton or other container, or on the same train, truck or other vehicle during their interstate journey. The packages and the circulars had a common origin and a common destination and arrived at their destination simultaneously. Clearly, therefore, they accompanied each other, regardless of whether, physically, they were together or apart during their journey.

"The defendant feels that this case supports her position because of the simultaneous arrival of the offending articles. The facts in UNITED STATES v. RESEARCH LABORATORIES, IND., supra, indicated a simultaneous arrival and that was as far as the Court was called upon to go. The Court's attitude towards a liberal interpretation of this Act is clearly brought out, when the Court further stated:

The rule of strict construction invoked by appellee has little or no application to statutes designed, as the Federal Food, Drug and Cosmetic Act, 21 U. S. C. A., Sec. 301 et seq., is designed, to prevent injury to the public health. A. O. ANDERSON & CO. v. UNITED STATES, 9 Cir. 284 Fed. 542, 543; UNITED STATES v. 48 DOZEN PACKAGES OF GAUZE, 2 Cir. 94 Fed. 2d., 641, 642.

"The second case that conforms to my conclusions is UNITED STATES v. LEE, 131 F. (2) 464. As in the case at bar, the circulars were shipped in interstate commerce separately from the products to which they relate. Therein the Court held as follows:

The word "accompany" is not defined in the Act, but we observe that among the meanings attributed to the word are "to go along with," "to go with or attend as a companion or associate," and "to occur in association with," Webster's New International Dictionary, 2d. Ed. There can be no question that among the usual characteristics of labeling is that of informing a purchaser of the uses of an article to which the labeling relates, and that the basic character of the Federal Food, Drug, and Cosmetic Act is not directly concerned with the sale of the products therein described, or whether the literature is carried away by the purchaser. It was enacted to protect the public health and to prevent fraud, and it ought to be given a liberal construction. Consequently, we are impelled to the conclusion that misbranding is cognizable under the Act if it occurs while the articles are being held for sale.

"The third case is UNITED STATES v. 7 JUGS etc., 53 Fed. Sup. 746, wherein an attempt was made to circumvent the Act by permitting a lapse of

time to occur between the shipment of the related articles. The Court disposed of this issue in the following language:

The physical aspects of the transportation are not important. What is vital here are such factors as interdependence of the drug and the booklets, common origin, common destination, display, distribution and use together. These determine whether there has been that degree of accompaniment which provides the necessary "misbranded" status under Section 304 (a). The mere fortuitous circumstance of an absence of physical association between the booklets and drugs during the interstate journey of the drugs does not in my opinion control.

"Besides the foregoing formidable authorities, common sense and reason dictates the same conclusion. The Act was primarily promulgated to protect the consuming public. (UNITED STATES v. TWO BAGS, etc., 147 F. (2) 123–127.) If that is true, what difference does it make in what manner the circular and drug made their interstate journey, so long as they eventually came together upon the merchant's shelf, there to mislead and defraud the consuming public? When the drug and related circular came together, the prohibited act occurred, irrespective of the circuitous route each may have traveled.

"The Act involved has with unanimity been liberally construed to protect the consuming public from the avaricious. U. S. v. 95 Barrels of Vinegar, 265 U. S. 438, 44 S. Ct. 529, 68 L. Ed. 1094; U. S. v. Antikamnia Chemical Co., 231 U. S. 654, 655, 34 S. Ct. 222, 58 L. Ed. 419; U. S. v. Schider, 246 U. S. 519, 522, 38 S. Ct. 369, 62 L. Ed. 863; A. O. Anderson and Co. v. U. S., 284 Fed. 542; C. C. Co. v. U. S., 147 Fed. (2) 820; U. S. v. Commercial Creamery Co., 43 Fed. Sup. 714.

"The defendant relies solely upon a strict interpretation of the statute invoking the principle set forth in the dissenting opinion of Mr. Justice Murphy in UNITED STATES v. DOTTERWEICH, 320 U. S. 277, and again in the recent opinion of the Supreme Court in M. KRAUSE & BROS. v. UNITED STATES, decided on March 25, 1946.

"The cases heretofore cited clearly indicate that our courts have not applied the usual rule of strict construction of criminal statutes to this Act, but have given it a liberal construction and thus enabled the Act to accomplish its remedial purpose of protecting public health and pocket book against misbranded foods and drugs.

Regard for these purposes should infuse construction of the legislation if it is to be treated as a working instrument of government, and not merely as a collection of English words. * * * But that is not the way to read legislation. Literalism and evisceration are equally to be avoided. [Mr. Justice Frankfurter in U. S. v. Dotterweich, 320 U. S. 277.]

All construction is the ascertainment of meaning. And literalism may strangle meaning. [Mr. Justice Frankfurter in Utah Junk Co. v. Paul A. Porter, etc., U. S., decided April 22, 1946.]

"If this Act is to be treated as a working instrument and not merely as a collection of English words, it must be interpreted as a living and vitalized Act. The defendant seeks, through literalism and evisceration, to avoid her studied attempt to circumvent the Act.

"I hold that the word 'accompany' as used in the Act means that when a drug and a related circular, having a common source and a common destination, come together at their destination, they are united and become one in so far as the buying public is concerned, each, in effect, accompanying the other, whether they arrived at their common destination simultaneously or otherwise.

"In view of my conclusions herein expressed, it is my opinion the drug described in Count XXIII was misbranded contrary to the provisions of the Federal Food, Drug and Cosmetic Act, and therefore the defendant is guilty as charged."

In accordance with the foregoing opinion, the defendant was found guilty and was sentenced to 3 years' probation on or about May 20, 1946. An appeal was taken to the United States Circuit Court of Appeals for the Ninth Circuit, and on January 31, 1947, the following opinion was handed down by that court, reversing the judgment of the district court:

DENMAN, *Circuit Judge:* "Appellant appeals from a judgment sentencing her to three years on probation for violation of the Federal Food, Drug, and Cosmetic Act, 21 U. S. C. 331 (a).

"The language of the information is that—

. . . Ada J. Alberty, . . . doing business . . . at Hollywood, Los Angeles, State of California, did . . . on or about April 18, 1944 *then and there,* in violation of the Act

of Congress . . . 21 U. S. C. 331 (a),[1] unlawfully introduce and deliver for introduction into interstate commerce, from Hollywood, Los Angeles, State of California, to Kansas City, State of Missouri, consigned to Natural Food Store, a certain consignment to wit, a number of bottles containing a drug within the meaning of 21 U. S. C. 321 (g) (2) . . .

That displayed upon written, printed, and graphic matter *accompanying said drug when introduced and delivered for introduction into interstate commerce,* as aforesaid, namely upon a number of leaflets entitled "So it's You again, is it?" relating to said drug which said leaflets were shipped by the said Ada J. Alberty trading and doing business as "Alberty Food Products" to said Natural Food Store *prior to the date of the shipment of said drug as aforesaid,* to wit, *on or about February 7, 1944,* were among other things the following statements: . . .

That said drug, when introduced and delivered for introduction into interstate commerce, as aforesaid, was *then and there* misbranded within the meaning of the said act of Congress [21 U. S. C. 352 (a)], in that the statements aforesaid appearing in the leaflets entitled "So it's You again, is it?" *accompanying* said drug, as aforesaid were false and misleading in this, that said statements represented and suggested that said drug would be efficacious to restore color to gray hair and would be efficacious to prevent hair from turning gray; whereas in fact and in truth said drug would not be efficacious to restore color to gray hair and would not be efficacious to prevent hair from turning gray. [Emphasis supplied.]

"Appellant demurred to the information on the ground that it does not charge an offense within the sections of the Federal Food, Drug, and Cosmetic Act, contending to the court below, as follows:

The Act in question (Secs. 343–a and 352–a of Title 21, U. S. C.) provides that a food or drug shall be deemed to be misbranded "if its labeling is false or misleading in any particular." Another section of the Act (Sec. 321–m of Title 21, U. S. C.) defines the term "labeling" to mean "all labels and other written, printed or graphic matter (1) upon any article or any of its containers or wrappers or (2) accompanying such article." . . .

and that the labels did not accompany the drug within Section 321 (m).

"The district court overruled the demurrer, thus ruling against appellant's contention that the literature did not accompany the drug when it was introduced into interstate commerce. Appellant assigns this ruling as error.

"Section 331 (a) provides

Prohibited acts

The following acts and the causing thereof are hereby prohibited:

(a) The introduction or delivery for introduction into interstate commerce of any food, drug, device, or cosmetic that is adulterated or misbranded. [Emphasis supplied.]

"It will be noted that the verb 'is' is in the present tense. Section 331 (a) confines the offense to a misbranding at the 'introduction or delivery for introduction into interstate commerce' as recognized in the information by the use of the words 'then and there.'

"A drug is misbranded 'If its labeling is false or misleading in any particular.' 21 U. S. C. 352 (a). 'Labeling' of an article is defined to mean 'all labels * * * accompanying such article.' 21 U. S. C. 321. (m).

"The information charges that the false labels were shipped by appellant to the Natural Food Store at Kansas City, Missouri, on February 7, 1944, that is two months and eleven days before April 18, 1944, when the drug was 'then and there' introduced into interstate commerce. It does not allege that the labels were to be placed with the drug or used together with it by the consignee. For all the information alleges, the labels may not have arrived in Missouri. Or they may have been destroyed. Or they may have been distributed to the prospective customers a month before the arrival of the drug in Missouri and hence never accompanied it there. Or they may have been used in connection with other drugs shipped and sold long prior to April 18, 1944, when the charged offense is alleged 'then and there' to have been committed.

"We do not think that the bald statement that the labels were shipped to the Missouri consignee seventy-one days before the drug was shipped charges the offense of causing them to be 'accompanying' the drug's introduction into interstate commerce on or about April 18, 1944.

"Appellee cites our decision United States v. Research Laboratories, Inc., (CCA 9), 126 F. 2d 42. In that case, a condemnation proceeding, the libel

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[1] There is another provision of the Act, 21 U. S. C. 331 (k), forbidding misbranding after the drug has passed through interstate commerce, as follows:

"(k) The alteration, mutilation, destruction, obliteration, or removal of the whole or any part of the labeling of, or the doing of any other act with respect to, a food, drug, device, or cosmetic, if such act is done while such article is held for sale after shipment in interstate commerce and results in such article being misbranded."

This section has no application to a charge that at the moment of introducing the drug into interstate commerce the misbranding "then and there" occurred.

charged that the false circulars accompanied the drug into interstate commerce and all arrived at their common destination simultaneously. The information in the instant appeal alleges no such facts and, on the contrary, cannot be construed as charging that the drug and labels were in interstate commerce at the same time, much less introduced therein at the same time. United States v. 7 Jugs of Dr. Salsbury's Rakos, 53 F. Supp. 746, has similar facts and follows the Research Laboratories case.

"Appellee also cites United States v. Lee, (CCA–7), 131 F. 2d 464. The complaint there sought an injunction because of an entirely different offense—the placing of the drug and false printed matter together *after* the interstate shipment in violation of 331 (k), referred to in our footnote above. It in no way supports the information purported to be based upon the claimed violation of 321 (m) at the time of shipment, to which appellant demurred.

"These three cases were civil proceedings and not criminal prosecutions. They construe the Act liberally. The question was raised at the hearing here whether in construing the Act as the basis of a criminal prosecution there should be a similar construction against the accused. Cf. the recent case of Kraus & Bros., Inc. v. United States, 327 U. S. 614, 621, construing in a criminal proceeding the Emergency Price Control Act which, like the Food, Drug, and Cosmetic Act, also afforded civil relief. There the Supreme Court states

> This delegation to the Price Administrator of the power to provide in detail against circumvention and evasion, as to which Congress has imposed criminal sanctions, creates a grave responsibility. In a very literal sense the liberties and fortunes of others may depend upon his definitions and specifications regarding evasion. Hence to these provisions must be applied the same strict rule of construction that is applied to statutes defining criminal action * * *

"However, we think that, whatever the criterion of construction, the ordinary use of the word 'accompanying' which we have here accepted is that applicable.

"After overruling the demurrer, the case was tried on a stipulation of facts which stated that the shipment of labels was received by the consignee on February 11, 1944, and the drug on April 25, 1944, clearly establishing that the two did not accompany each other when introduced into interstate commerce nor at any time in that interstate transit. It was also stipulated that they were exhibited together in the consignee's store. Here there might be said to be accompaniment *after* the interstate commerce was completed, but nothing is stipulated as to appellant's then ownership or control of the drug and labels or her participancy in these later acts to bring her within 331 (k), a section not involved in the information.

"The judgment is reversed, the case is remanded, and the information ordered to be dismissed."

2376. Misbranding of solution of magnesia sulfate with citrate of magnesia. U. S. v. Roma Extract Co., Vincenzo Contrino, and Joseph Graceffa. Pleas of guilty. Fine of $50 against each defendant. (F. D. C. No. 23581. Sample Nos. 57179–H, 57635–H.)

INFORMATION FILED: May 5, 1948, District of Massachusetts, against the Roma Extract Co., a partnership, Boston, Mass., and Vincenzo Contrino and Joseph Graceffa, partners.

ALLEGED SHIPMENT: On or about June 13 and December 30, 1946, from the State of Massachusetts into the State of Rhode Island.

NATURE OF CHARGE: Misbranding, Section 502 (a), the words "Citrate Magnesia" molded into the bottles of the article and "Citrate of Magnesia" appearing on the shipping cartons were false and misleading, in that such words represented and suggested that the article consisted of solution of magnesium citrate, commonly known as citrate of magnesia, whereas the article was essentially a solution of epsom salt; Section 502 (i) (1), the container of the article was so made and formed as to be misleading, in that the container resembled the bottle commonly used as a container for citrate of magnesia and bore the words "Citrate Magnesia" molded into the glass; and, Section 502 (i) (2), the article was an imitation of another drug, "Solution of Magnesium Citrate," commonly known to the trade and the public as citrate of magnesia.

DISPOSITION: June 8, 1948. Pleas of guilty have been entered, the court imposed a fine of $50 against each defendant.

2377. Misbranding of D–M–C Prescription No. 49, D–M–C Tonic, D–M–C Anodyne Medicine Compound, D–M–C Levorette Tonic, and D–M–C Levorette Tablets. U. S. v. Dixie Medicine Corp. Plea of nolo contendere. Judgment suspended, conditioned upon defendant's action in changing the labels of the products; case subsequently dismissed without imposition of sentence. (F. D. C. No. 11354. Sample Nos. 35416–F, 35417–F, 35419–F to 35421–F, incl.)

INFORMATION FILED: March 28, 1944, Western District of North Carolina, against the Dixie Medicine Corp., Charlotte, N. C.

ALLEGED SHIPMENT: On or about March 5 and April 8, 1943, from the State of North Carolina into the State of South Carolina.

PRODUCT: Analyses disclosed that the *D-M-C Prescription No. 49* consisted essentially of compounds of sodium and potassium, tartrates, sulfur, senna, licorice, and 2.11 percent of sodium salicylate; that the *D-M-C Tonic* consisted essentially of a small proportion of an iron compound and extracts of plant drugs including nux vomica, water, and 3.7 percent of alcohol; that the *D-M-C Anodyne Medicine Compound* consisted essentially of small proportions of ammonium salt, camphor, volatile oil, and extracts of plant drugs including ginger, alcohol 5.0 percent, and water; that the *D-M-C Levorette Tonic* consisted essentially of epsom salt, extracts of plant drugs including emodin bearing drugs, a compound of iron, alcohol 1.5 percent, and water; and that the *D-M-C Levorette Tablets* contained calomel in the proportion of 0.47 grain per tablet and extracts of plant drugs including capsicum and colocynth.

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements on the labels of the articles were false and misleading, since the articles would not be efficacious for the purposes represented. The labels represented that the *D-M-C Prescription No. 49* would be efficacious in the cure, mitigation, treatment, and prevention of arthritis and rheumatism and would produce a remedial effect in rheumatism and arthritis in two weeks; that the *D-M-C Tonic* would be efficacious in the cure, mitigation, treatment, and prevention of loss of appetite, lack of vitality, and nervousness, and would be an efficacious purifier for the blood; that the *D-M-C Anodyne Medicine Compound* would be efficacious in the cure, mitigation, treatment, and prevention of dysentery, diarrhea, summer complaint, cholera morbus, flux, and pains in the stomach or bowels; that the *D-M-C Levorette Tonic* would be efficacious in the cure, mitigation, treatment, and prevention of colds, sick headaches, and all ills caused by an inactive liver; and that the *D-M-C Levorette Tablets* would be efficacious to regulate the liver.

Further misbranding, Section 502 (a), the statements on the labels of the *D-M-C Anodyne Medicine Compound* and the *D-M-C Levorette Tonic* which represented that the compound contained 7 percent of alcohol and that the tonic contained 5 percent of alcohol were false and misleading, since the compound contained not more than 5 percent of alcohol and the tonic contained not more than 1.5 percent of alcohol.

DISPOSITION: On April 17, 1944, an answer was filed on behalf of the defendant, denying the allegations of the information. Thereafter, a pre-trial conference was held, a result of which the court found as facts (1) that the defendant had changed and modified all labels on the products complained of and had used the changed and modified labels since making such changes and (2) that the defendant agreed to make further changes in its labels. On October 11, 1944, the court held that the new label of the *D-M-C Prescription No. 49* could be continued by striking out "Due To Arthritis, Rheumatism and Muscular Aches" and substituting the words "Muscular Aches and Pains"; that the new label of the *D-M-C Tonic* containing the statements "Intended to Help Increase the Appetite and as a tonic when lack of iron is indicated" could be continued, provided that the defendant increase the proportion of iron in the product; that the use of the *D-M-C Anodyne Medicine Compound* should be discontinued and stocks of such product withdrawn from the market; that the new label of the *D-M-C Levorette Tonic*, which designated such product as "Laxative Compound," could be continued by striking out the words "May be found helpful in relieving simple colds and headaches"; and that the new label of the *D-M-C Levorette Tablets*, which designated such product as "Laxative Tablets," could be continued upon striking out the words "and Regulation of the Bowels." Following this decision of the court, the defendant entered a plea of nolo contendere and the court suspended judgment. On April 7, 1947, the court was informed that there was no evidence

to indicate that the defendant was failing to comply with the decision of October 11, 1944, and the case was thereupon dismissed without imposition of sentence.

2378. Misbranding of Estromone. U. S. v. Endo Products, Inc. Plea of guilty. Fine, $900. (F. D. C. No. 17848. Sample Nos. 31429–H, 31442–H, 31443–H.)

INFORMATION FILED: March 17, 1947, Eastern District of New York, against Endo Products, Inc., Richmond Hill, N. Y.

ALLEGED SHIPMENT: On or about March 31 and May 10, 1945, from the State of New York into the State of California.

LABEL, IN PART: "Endo Estromone."

NATURE OF CHARGE: Misbranding, Section 502 (a), the label statements "Estrogenic Substance Derived from Equine Urine" and "Estrogenic Substance derived from pregnant mares' and stallions' urine" were false and misleading. The statements represented and suggested that the estrogenic material present in the article was estrogenic substance as it occurs in and is extracted from natural sources, i. e., pregnant mares' and stallions' urine and equine urine. The estrogenic material present in the article was not estrogenic substance as it occurs in and is extracted from natural sources.

Further misbranding, Section 502 (e) (2), the article was not designated solely by a name recognized in an official compendium and was fabricated from two or more ingredients, and its label failed to bear the common or usual name of each active ingredient, since the designation "Estrogenic Substance" is not the specific name of any particular substance but is a generic name for a class of substances.

DISPOSITION: May 20, 1948. A plea of guilty having been entered, the court imposed a fine of $300 on each of the three counts of the information.

2379. Misbranding of mixed estrogenic substance in oil. U. S. v. 38 Cartons * * *. (F. D. C. No. 23975. Sample No. 22487–K.)

LIBEL FILED: November 17, 1947, Western District of Texas.

ALLEGED SHIPMENT: On or about October 15, 1947, by Henry C. Haist & Co., from Kansas City, Mo.

PRODUCT: 38 cartons, each containing 1 30-cc. vial, of *mixed estrogenic substance in oil* at San Antonio, Tex.

LABEL, IN PART: (Vial) "30 CC. Multiple Dose Vial Mixed Natural Estrogenic Substance in Oil 10,000 International Units Per CC."; (carton) "10,000 I. U. Per CC. * * * Manufactured for M. L. Claytor & Company San Antonio, Texas."

NATURE OF CHARGE: Misbranding, Section 502 (a), the label statements "Mixed Natural Estrogenic Substance in Oil 10,000 International Units [or "10,000 I. U."] Per CC. * * * A solution of mixed natural occurring estrogens, derived from pregnant mare's urine, consisting principally of estradiol and estrone, in sesame oil. Rated as estrone." were false and misleading, since the statements represented and suggested that the article consisted of a solution in oil of estrogens obtained from pregnant mares' urine equivalent in potency to 10,000 International Units of estrone per cubic centimeter, whereas the article did not possess such composition.

DISPOSITION: January 23, 1948. Default decree of forfeiture and destruction.

2380. Misbranding of Marcillin. U. S. v. 7 Jugs * * *. (F. D. C. No. 23089. Sample No. 91872–H.)

LIBEL FILED: June 25, 1947, District of New Mexico.

ALLEGED SHIPMENT: On or about April 15, 1947, by Metabolic Research Laboratories, from Detroit, Mich.

PRODUCT: 7 1-gallon jugs of *Marcillin* at Central, N. Mex. Examination showed that the product consisted essentially of material extracted from bile dissolved in water.

NATURE OF CHARGE: Misbranding, Section 502 (a), the label statements "Physiologically active by skin absorption * * * A skin inunction treatment, useful in protein deficiency and biliary deficiency states; also in specific, virogenic, metabolic and allergic infections or syndromes" were false and misleading, since bile is not physiologically active by skin absorption and is not

effective by inunction in treatment of protein deficiencies and biliary deficiency states, and in specific, virogenic, metabolic, or allergic infections and syndromes.

DISPOSITION: April 1, 1948. Default decree of condemnation and forfeiture. The product was subsequently destroyed.

2381. Misbranding of Ostabs Antiseptic Mouthwash Tablets. U. S. v. 41 Bottles, etc. (F. D. C. No. 23986. Sample No. 18218–K.)

LIBEL FILED: November 28, 1947, Northern District of Ohio.

ALLEGED SHIPMENT: On or about September 8, 1947, by Ostab Laboratories, Inc., from Buffalo, N. Y.

PRODUCT: 41 125-tablet bottles, 82 50-tablet bottles, and 168 20-tablet bottles of *Ostabs Antiseptic Mouthwash Tablets* at Cleveland, Ohio. Examination showed that the product was not antiseptic when prepared as directed, i. e., "Dissolve One Ostab Tablet in Glass of Water and Stir."

NATURE OF CHARGE: Misbranding, Section 502 (a), the label statement "Ostabs Antiseptic Mouthwash Tablets" was false and misleading as applied to an article which was not antiseptic.

DISPOSITION: April 7, 1948. Default decree of condemnation and destruction.

2382. Misbranding of Ultra-Tone Magic Salve. U. S. v. 87 Tubes, etc. (F. D. C. No. 23953. Sample Nos. 33014–K, 33015–K.)

LIBEL FILED: November 7, 1947, Northern District of California.

ALLEGED SHIPMENT: On or about July 15, 1947, by the Ultra Chemical Products, from Honolulu, Hawaii.

PRODUCT: 87 ½-ounce tubes and 27 14-gram tins of *Ultra-Tone Magic Salve* at San Francisco, Calif. Examination showed that the product contained salicylic acid, benzoic acid, and boric acid, in a petrolatum base.

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements on the label of the article were false and misleading, since they represented and suggested that the article was efficacious in the treatment and prevention of fungi itch, barbers' itch, insect bites, ringworm, pimples, scabies, eczema, boils, cuts, itchy skin, scaly skin conditions, and irritations caused by external factors, whereas the article was not efficacious in the treatment and prevention of such disease conditions.

DISPOSITION: February 27, 1948. Default decree of condemnation and destruction.

2383. Misbranding of A–1 Salve No. 2, A–1 Salve, and A–1 Sulphur Soap. U. S. v. 66 Cartons, etc. (F. D. C. No. 23189. Sample Nos. 71144–H to 71149–H, incl.)

LIBEL FILED: June 13, 1947, Southern District of California.

ALLEGED SHIPMENT: From Chicago, Ill., by the Wizard Products Co. The products were shipped on or about April 7 and May 9, 1947, and a number of placards were shipped on or about February 7 and April 7, 1947.

PRODUCT: 134 cartons each containing a circular headed "A–1 Salve No. 2" and one 2-ounce or 4-ounce jar of *A–1 Salve No. 2*, 287 cartons each containing a circular headed "A–1 Salve" and one jar of *A–1 Salve*, and 60 cartons, each containing one cake, of *A–1 Sulphur Soap* at Los Angeles, Calif., together with a number of placards headed "Skin Disorders or Mycotic Infections," "Wizard Products Company Try A–1 Salve," and "Use A–1 Sulphur Soap." Analyses disclosed that the *A–1 Salve No. 2* was an ointment containing a fatty oil, lanolin, ichthammol, and a small proportion of a manganese compound; that the *A–1 Salve* was an ointment containing petrolatum, lanolin, sulfur, salicylic acid, zinc oxide, and chemically combined iodine; and that the *A–1 Sulphur Soap* was soap mixed with sulfur.

NATURE OF CHARGE: *A–1 Salve No. 2* (2-ounce size). Misbranding, Section 502 (a), certain statements in the circular enclosed with the jars of the article were false and misleading, since they representend and suggested that the article was effective for ulcers due to infections; that it was effective by reason of its ichthammol content in a large variety of skin diseases, especially in acne and furunculosis; that it contained tannic acid, which is the standard treatment for all serious burns; that affected areas of the skin treated with the article would be remedied rapidly; and that the article would be useful in the

self-treatment of ulcer-like growths, such as cancers, diabetic sores, and varicose vein ulcers. The article was not effective for the purposes represented; tannic acid is not the standard treatment for all serious burns; affected areas of the skin treated with the article would not be remedied rapidly; and the article would not be useful in the self-treatment of ulcer-like growths, such as cancers, diabetic sores, and varicose vein ulcers. Further misbranding, Section 502 (a), certain statements on the label were misleading, since they created the impression that the use of the article would be efficacious in the self-treatment of the disease conditions mentioned, whereas the article would not be efficacious in the self-treatment of the following conditions: "Such skin disorders as ulcers, varicose ulcers, diabetic ulcers, weeping eczema and others, are serious conditions usually internally caused, and require the attention of a dermatologist or other physician. But meanwhile the irritation may be temporarily relieved and the discomforts allayed by the application of A–1 Salve No. 2 * * * Attention: After initial cleansing of affected area, progress will be more rapid if water and soap can be eliminated during the use of the salve."

A–1 Salve. Misbranding, Section 502 (a), the statement in the circular enclosed with the article, which represented and suggested that the article was effective in the treatment of conditions due to systemic causes, was false and misleading, since the article was not effective for such purpose.

A–1 Salve No. 2 (2- and 4-ounce sizes), and *A–1 Salve.* Misbranding, Section 502 (a), the statement "Pompholyx" and the photographs purporting to show feet before and after treatment of this skin disorder with *A–1 Salve*, appearing on an accompanying placard, were misleading, since the statement and photographs represented and suggested that the articles were effective in the treatment of pompholyx, whereas they were not effective for such purposes. Further misbranding, Section 502 (a), certain statements and designs on accompanying placards, i. e., "Skin Disorder's * * * Varicose Ulcer Weeping Eczema Psoriasis Alopecia Eczema * * * Try A–1 Salve" and "Varicose Ulcer Psoriasis Food Allergy Alopecia Eczema" and photographs showing such skin disorders, were misleading since the statements and designs represented and suggested that the articles were effective in the treatment of such conditions, whereas the articles were not effective for such purpose; and the misleading impression created by the statements and designs was not corrected by the following statements which were printed in small, relatively inconspicuous type, since it was obvious that the purpose in presenting the photographs was to induce purchasers to use the articles for the treatment of the conditions depicted: "These are photographs of limbs afflicted with Varicose Ulcers and Weeping Eczema. Such cases are due to systemic causes which require the attention of a physician. If an ointment is indicated as a dressing by the attending physician we suggest the use of A–1 SALVE No. 2." and "These are pictures of acute cases of Psoriasis, Alopecia, and Eczema. They may become chronic and require the services of a competent physician. In such cases, if the physician advises the use of an ointment as a dressing, we suggest the use of A–1 SALVE."

A–1 Sulphur Soap. Misbranding, Section 502 (a), the following statements in the labeling of the article were misleading: (Carton) "A–1 Sulphur Soap * * * is intended to help in Parasitic Infections" and (placard) "Use A–1 Sulphur Soap A special preparation * * * intended to help in Parasitic Infections." The statements represented and suggested that the article constituted an adequate treatment for parasitic infections, whereas the article did not constitute an adequate treatment for such conditions.

DISPOSITION: July 30, 1947. Default decree of condemnation and destruction.

2384. Misbranding of Scalp-Eez. U. S. v. 12 Cartons * * *. (F. D. C. No. 22658. Sample No. 81420–H.)

LIBEL FILED: March 3, 1947, Western District of Washington.

ALLEGED SHIPMENT: On or about November 21, 1946, by Scalp-Eez, Inc., from Martinez, Calif.

PRODUCT: 12 cartons, each containing 1 4-ounce jar, of *Scalp-Eez* at Vancouver, Wash. Examination showed that the product consisted essentially of sulfur, volatile oils such as oil of cade, with small proportions of an iodide and quinine incorporated in an ointment base.

NATURE OF CHARGE: Misbranding, Section 502 (a), the labeling of the article was false and misleading, since it represented and suggested that the article

was effective to grow hair, to prevent falling hair, to correct dandruff, and to revitalize the scalp. The article was not effective for such purposes.

Further misbranding, Section 502 (e) (2), the article was fabricated from two or more ingredients, and the carton label failed to bear the common or usual name of each active ingredient.

DISPOSITION: March 15, 1948. Scalp-Eez, Inc., claimant, having failed to file an answer to the libel or otherwise plead, judgment of condemnation was entered and the product was ordered destroyed.

2385. Misbranding of Autolift Bust Developers. U. S. v. 303 Autolift Bust Developers, etc. (F. D. C. No. 24466. Sample No. 14113–K.)

LIBEL FILED: March 18, 1948, Northern District of Illinois.

ALLEGED SHIPMENT: On or about January 30, 1948, by the Flexsaw Co., from Port Austin, Mich.

PRODUCT: 303 *Autolift Bust Developers* at Chicago, Ill., together with a number of circulars entitled "Instruction For Using The Autolift." Examination showed that the product consisted of two plastic cups, ribbon and body strap, and a suction pump with rubber tubing.

NATURE OF CHARGE: Misbranding, Section 502 (a), the following statements in the circular were false and misleading, since the article was not effective in developing the busts: "Autolift Bust Developer. This scientifically designed instrument works on Nature's own principle, suction. This action massages the muscular structure of the breast and stimulates the flow of blood to the desired area. The proper use of this developer will well pay for the trouble, in giving a fuller, rounder, firmer bust. Really an investment in beauty and marital happiness. * * * Exercise busts each night before retiring for best results."

DISPOSITION: May 7, 1948. Default decree of condemnation and destruction.

2386. Misbranding of Burnett's Radio-Active Emanator. U. S. v. 12 Cones * * *. (F. D. C. No. 23710. Sample No. 49567–H.)

LIBEL FILED: September 23, 1947, Southern District of Mississippi.

ALLEGED SHIPMENT: On or about February 1947, by W. H. Burnett, from Kingsland, Ark.

PRODUCT: 12 devices represented as "Burnett's Radio-Active Emanator" at Decatur, Miss., together with a number of accompanying circulars entitled "Nature's Health Restorer" and "Burnett's Radio-Active Emnator A Health Spring in Your Home." The device was an olive drab-colored solid 10-sided pyramid, about 4½ inches wide at its base and standing about 6 inches high. It consisted of a molded concrete block containing a trace of radioactive material, too little to be of any therapeutic significance.

NATURE OF CHARGE: Misbranding, Section 502 (a), the article was represented by the circulars to be effective in the treatment of kidney disorders, diabetes, high blood pressure, stomach troubles, rheumatism, arthritis, asthma, and other kindred troubles, whereas it was useless for such purposes.

DISPOSITION: March 16, 1948. Default decree of condemnation and destruction.

2387. Misbranding of Chlorogen devices. U. S. v. 5 Devices, etc. (F. D. C. No. 23866. Sample Nos. 15007–K, 15008–K.)

LIBEL FILED: October 24, 1947, Eastern District of Michigan.

ALLEGED SHIPMENT: On or about September 2 and 11, 1947, by the Chlorogen Co., from Phoenix, Ariz.

PRODUCT: 5 *Chlorogen devices* at Detroit, Mich., together with a number of pamphlets entitled "Chlorogen Therapy" and one set of operating instructions entitled "Chlorogen Chlorine Gas Generating Inhalator," which were shipped with the devices. Examination of the article showed that it was an electrical device for the production of chlorine.

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements in the labeling of the device were false and misleading, since they represented and suggested that the device when used as directed was effective in the treatment of sinus infections, upper respiratory diseases, rheumatoid (infectious) arthritis and internal diseases secondary to toxicosis from nasal mucous and sinus infections, sore throat, inflamed tonsils, large goiter, migraine headaches, asthma, sinusitis, bronchitis, and common colds. The device when used as

directed was not effective in the treatment of such diseases, conditions, and symptoms.

DISPOSITION: April 28, 1948. Default decree of condemnation. The product was ordered delivered to the Food and Drug Administration, for clinical and experimental uses.

2388. Misbranding of Cosmo-Light device. U. S. v. 1 Device, etc. (F. D. C. No. 22289. Sample No. 70813–H.)

LIBEL FILED: February 18, 1947, Southern District of California.

ALLEGED SHIPMENT: On or about November 15, 1946, by Dr. Fred Gerkey, from Kansas City, Mo.

PRODUCT: 1 *Cosmo-Light device*, together with two accessory applicators at Glendale, Calif., and a leaflet headed "Instructions," which was shipped with the device. The device consisted of tubes for producing colored lights similar to the so-called neon lights, together with the electrical connections needed to operate them.

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements in the labeling of the article were false and misleading, since they represented and suggested that the device was effective when used as directed in the treatment of asthma, every kind of a condition, nervousness, eye troubles, female diseases, and sinus trouble. The article was not effective when used as directed in the treatment of such conditions.

DISPOSITION: On April 3, 1947, an order was entered directing that the case be removed for trial to the Western District of Missouri. On March 18, 1948, the interveners withdrew their claim and answer, and on April 16, 1948, judgment of condemnation was entered and the product was ordered delivered to the Food and Drug Administration, for use as an educational exhibit.

2389. Misbranding of Spectro-Chrome. U. S. v. Dinshah P. Ghadiali and Dinshah Spectro-Chrome Institute. Pleas of not guilty. Tried to the jury. Verdict of guilty. Institute fined $12,000. Individual fined $8,000; sentenced to 1 year in jail on each of first 3 counts, the execution of which sentence was suspended, and placed on probation for 5 years; imposition of sentence on last 4 counts suspended. Judgment affirmed on appeal to United States Circuit Court of Appeals. Petition for writ of certiorari denied by United States Supreme Court. (F. D. C. No. 16547. Sample Nos. 76870–F, 76872–F, 82254–F, 85045–F, 4061–H, 4094–H, 4174–H, 4175–H, 13743–H, 13887–H, 16303–H, 23316–H.)

INDICTMENT FILED: August 7, 1945, District of New Jersey, against Dinshah P. Ghadiali and Dinshah Spectro-Chrome Institute, a corporation, Malaga, N. J.

ALLEGED SHIPMENT: Between September 3, 1942, and July 9, 1945, from the State of New Jersey into the States of New York, Pennsylvania, Ohio, Wisconsin, Michigan, Missouri, and Delaware.

PRODUCT: The construction and appearance of the device is described in the quoted court opinion set forth below.

Each device was accompanied by one or more of the following pieces of printed and graphic matter: "Spectro-Chrome Home Guide," "Rational Food of Man," "Favorscope," "Spectro-Chrome, December 1941 Issue," "Spectro-Chrome, May [or "August,"] 1944 Issue," "Spectro-Chrome in Every Home," "Key to Radiant Health," "Auxiliary Benefit Notice," "Request for Enrollment as Benefit Student," "Certificate of Benefit Studentship," "Spectro-Chrome Free Guidance Request," "Spectro-Chrome Free Guidance," "Spectro-Chrome, March 1945 Issue," "Spectro-Chrome, January 1945 Issue," "Spectro-Chrome Metry Encyclopedia—Volumes 1, 2, and 3," and "Here is the Work that Shattered All the False Conceptions in Healing."

NATURE OF CHARGE: Misbranding, Section 502 (a), the labeling of the device contained false and misleading curative and therapeutic claims in substantially the same respect as the device involved in notices of judgment on drugs and devices, No. 2098.

DISPOSITION: Following the entry of pleas of not guilty, the case came on for trial before the court and jury on October 21, 1946. The trial was concluded on January 7, 1947, at which time the jury returned a verdict of guilty. Motions for a directed verdict of acquittal and for a new trial were filed on behalf of the defendant on January 13, 1947, and after consideration of the arguments for and against such motions, the court, on January 22, 1947, denied the motions. On January 31, 1947, the court imposed the following sentences: (1) Against the institute, a fine of $12,000; (2) against the individual de-

fendant, a fine of $1,000 on each of counts 1, 2, and 3, and imprisonment of 1 year on each of those counts, to run consecutively, with execution of the jail sentences to be suspended; a fine of $1,000 on each of counts 4, 5, 6, 7, and 8; and imposition of sentence suspended on counts 9, 10, 11, and 12, and probation for 5 years. Under the terms of probation, the individual defendant was directed to disassociate himself directly and indirectly from the promotion of *Spectro-Chrome*, or Spectro-Chrome Metry, its teaching and literature, and so forth, in every form under which it might be projected; to dissolve the corporation known as Dinshah Spectro-Chrome Institute; to turn over all the literature to the Government for destruction; to discontinue directly or indirectly the services of free guidance and the editing of the magazine; and to freely and voluntarily open his books and records at reasonable times to the inspection of the proper officers of the Government in control of the matter.

Following imposition of sentence, an appeal was taken on behalf of the defendants to the United States Circuit Court of Appeals for the Third Circuit, and on January 9, 1948, the following decision was handed down by that court:

MARIS, MCLAUGHLIN, AND KALODNER, *Circuit Judges*: "The defendants have appealed from their conviction in the district court for the district of New Jersey upon twelve counts of an indictment charging them with introducing into interstate commerce in violation of the Federal Food, Drug and Cosmetic Act (21 U. S. C. A. chap. 9), certain devices known as Spectro-Chromes intended for use in the cure, mitigation, treatment and prevention of disease in man which were misbranded. The devices in question consisted of a cabinet equipped with a 1000 watt electric light bulb, an electric fan and water container for cooling purposes, two glass condenser lenses to focus the rays from the electric light bulb and five ordinary glass slides, each of a different color. Attached to the devices were plate labels bearing, in part, the following:

SPECTRO-CHROME METRY
MEASUREMENT AND RESTORATION OF THE HUMAN
RADIO-ACTIVE AND RADIO-EMANATIVE EQUILIBRIUM
(NORMALATION OF IMBALANCE)
BY
ATTUNED COLOR WAVES
THE SCIENCE OF AUTOMATIC PRECISION
NO DIAGNOSIS—NO DRUGS—NO MANIPULATION—NO SURGERY
ORIGINATED, DEVELOPED, APPLIED, COPYRIGHTED 1920 BY
COLONEL DINSHAH P. GHADIALI, M. S. C., M. D., M. E., D. C., PH. D., L. L. D.,
N. D., D. OPT., D. F. S., D. H. T., D. M. T., D. S. T., ETC.
METAPHYSICIAN AND PSYCHOLOGIST

"The devices were accompanied by various pieces of printed matter, two of them being entitled in part 'Spectro-Chrome Home Guide' and 'Favorscope," which related to the devices and contained statements relative to their therapeutic value in the cure, mitigation, treatment or prevention of disease, and directions for their use. The directions called for doing what the defendants call 'irradiating' the body of the patient with what the defendants describe as 'attuned color waves' projected by the device through the colored glass slides. The particular slide or combination of slides required to produce the exact color said to be needed to treat a given disorder was specified in the 'Spectro-Chrome Home Guide.' The patient was advised to adhere to a designated diet. He was directed to subject himself to 'irradiation' while facing south or lying in a north and south position with his head to the north. The 'tonations' from the Spectro-Chrome were to be taken at times specified by the defendants in the 'favorscope' which accompanied the device and which, they alleged, was compiled on the basis of solar, lunar and terrestrial radiant, gravitational influence.

"The government presented a large amount of evidence which, if believed, was amply sufficient to support a finding by the jury that the labeling of the defendants' Spectro-Chrome device was false and misleading within the meaning of Sec. 502 (a) of the Federal Food, Drug and Cosmetic Act (21 U. S. C. A. § 352 (a)) in that the device did not have the therapeutic value which the labeling claimed for it. The jury, evidently believing the government's evidence, found the defendants guilty of violating the act. The defendants upon the present appeal have presented eleven points which they assert require the reversal of the judgment of the district court. We have examined with care each of the points raised by the defendants and we find each to be wholly lacking

in merit. It would serve no useful purpose to discuss them in detail. Suffice it to say that our consideration of the case has left us completely satisfied that the defendants had a fair trial. Indeed the trial judge, if anything, leaned over backward to afford them the fullest opportunity to establish their defense and he submitted their case to the jury in a charge to which no objection was or fairly could be made.

"The judgment of the district court will be affirmed."

A petition for writ of certiorari was filed subsequently in the Supreme Court of the United States on behalf of the defendants, and on May 17, 1948, the appeal for such writ was denied.

2390. Misbranding of Spectro-Chrome. U. S. v. 1 Device * * *. Decree of dismissal reversed upon appeal. Petition for certiorari denied by U. S. Supreme Court. Decree of condemnation and destruction. (F. D. C. No. 16781. Sample No. 4163–H.)

LIBEL FILED: July 26, 1945, District of Oregon.

ALLEGED SHIPMENT: On or about June 14, 1945, from Newfield, N. J., by Dinshah Spectro-Chrome Institute.

PRODUCT: 1 *Spectro-Chrome* device at Portland, Oreg., together with a number of pieces of printed and graphic matter which were shipped with the device and which were entitled "Spectro-Chrome Home Guide," "Favorscope for 1945," "Rational Food of Man," "Key to Radiant Health," "Request for Enrollment as Benefit Student," "Auxiliary Benefit Notice—Make Your Own Independent Income as Our Introducer," "Spectro-Chrome General Advice Chart for the Service of Mankind—Free Guidance Request," "Certificate of Benefit Studentship," "Spectro-Chrome—December 1941—Scarlet," and "Spectro-Chrome—March 1945—Yellow." The construction and appearance of the device was essentially the same as the device involved in the case which was reported in notices of judgment on drugs and devices, No. 2098.

NATURE OF CHARGE: Misbranding, Section 502 (a), the labeling of the device contained false and misleading curative and therapeutic claims in substantially the same respect as the device involved in the above-mentioned notice of judgment, No. 2098.

DISPOSITION: Following the seizure of the device, William Ray Olsen, Portland, Oreg., appeared as claimant and filed an answer on August 31, 1945, alleging that he was the owner of the device and that it had been unlawfully and forcibly seized and taken from his possession in his home, over his protests and against his consent. The claimant alleged also that the device was not subject to the jurisdiction of the court and that it was not misbranded. On February 20, 1946, a motion was made on behalf of the Government for an order directing that the colored slides of the device be detached and delivered to the Food and Drug Administration for the purpose of scientific examination. After consideration of the argument and briefs of counsel, the court, on April 4, 1946, handed down the following memorandum opinion:

MCCOLLOUCH, *District Judge:* "Because I was told that the Department of Justice was making this a test case for many similar cases throughout the country, I took some time before ruling, although it seemed plain to me at the outset that defendant's constitutional rights had been invaded.

"Defendant has purchased a Spectro-Chrome for the use of himself and his mother. The prospectus promises many cures. A color, or a combination of colors, will cure this, another combination of color will cure that. The Government obtained a judgment that the machine was fraudulent in proceedings against the manufacturer and, because this machine was shipped in interstate commerce, the Government claims the right to take it from defendant, though he has bought and paid for it and is using it in his home. In fact, the Marshal now has the machine in his possession, and this is a motion by the Government for permission to dismantle the machine for examination.

"On what conceivable basis, under our Constitutional guaranties can the Government deny to an adult individual the right to believe in and seek to cure himself of physical ailments by any means he chooses, so long as the means chosen is not inherently dangerous or harmful? I know many people who wear charms, including some who carry the lowly potato, to keep diseases away, and I had always thought they had the right to do this. Incidentally, I have no doubt that many get help in this manner.

"I have not mentioned the special guaranties afforded by our law against intrusion into the home. This ground, I feel confident, could be shown to be sufficient to denounce the seizure in this case as unlawful.

"Since writing what is above I have been advised that the Government is contemplating dismissing the case and returning the Spectro-Chrome to defendant's home. If that is done, it is likely that nothing more will need to be said.

"The Government's motion is denied."

On April 23, 1946, the claimant filed a motion to quash the warrant of seizure, to restore the seized device to the claimant, and to dismiss the libel proceedings. Arguments of counsel on the motion were heard by the court, and on April 29, 1946, an order was entered directing that the seized article of device be returned to the claimant. On May 21, 1946, the case came on for trial before the court without a jury, at which time the court denied the Government's motions for summary judgment and for an order for the production of the device in court. At the conclusion of the trial on May 22, 1946, the court rendered the following opinion:

McCollouch, *District Judge:* "This case having now been tried on the merits revives the question whether an inanimate object, inherently non-dangerous, which the owner thinks has therapeutic value, can be taken from him and his home, under process pursuant to the Federal Food and Drugs Act.

"It has been stipulated that the device was shipped in interstate commerce, labeled with false and misleading statements as to its therapeutic capabilities. Regardless, the owner testified that he was satisfied with the machine and wanted to keep it, and that he and his mother had both obtained help for certain disorders by using the machine. He testified further that he did not intend to make commercial use of the machine, did not intend to permit it to be used outside of his home, or by others than his immediate family, constituting his parents and two brothers, both over twenty-one years of age and having had the same education as Claimant, in the grammar and high schools of the city of Portland, Oregon. The Claimant is twenty-three years old and was employed during the war in aircraft production, where he made use of the education which he had received in technical high school.

"The Government relies on the words of the statute, that an article introduced into interstate commerce, with fraudulent representations as to its therapeutic value, may be seized and condemned 'while in interstate commerce or at any time thereafter. . . .' 21 U. S. C. Sec. 334 (a). The underlined words, the Government contends, permit it to pursue and seize the article and the literature containing the misleading statements, in a private home.

"As shown by an earlier memorandum, the article was seized by the Marshal on initial process, but I must now add that prior to the trial on the merits just concluded, and subsequent to the preliminary memorandum, I directed that the Spectro-Chrome be returned to Claimant's home—so that the case might present, as it now does, the clear cut issue, whether an instrument, harmless in itself, but accompanied by misleading literature as to the capabilities of the instrument, may be seized against his will from an adult male person, compos, who states that he is satisfied with the machine, is being helped by its use, and wishes to keep it.

"I think this issue has not before been directly presented and I think, as Judge Cooley said many years ago, that the question is—does this case constitute an exception to the general rule that the citizen's home is his castle, the security of which he may defend against all trespass? The Government has a heavy burden to establish the exception.

> Near in importance to exemption from any arbitrary control of the person is that maxim of the common law which secures to the citizen immunity in his home against the prying eyes of the government, and protection in person, property, and papers against even the process of the law, except in a few specified cases. * * * [p. 425.]
> * * * it would generally be safe * * * to regard all those searches and seizures "unreasonable" which have hitherto been unknown to the law, and on that account to abstain from authorizing them, leaving parties and the public to the accustomed remedies. [p. 433.]
> [Constitutional Limitations, 7th Ed.]

"This case does not present such an exception. The case is nothing more than a well intentioned effort by high-minded and zealous officials to protect a man from what they deem to be folly, to the extent of following him into his home and family and there divesting him of property. This cannot be done, and I regret that I find myself in dissent from those Districts where, in con-

nection with the nation-wide campaign to retrieve Spectro-Chrome machines, wherever found, contempt orders have been issued to private owners to compel delivery for condemnation.

"To me, the wisdom of the ages means nothing if this humble citizen can be compelled against his will to yield access to his home to Federal officers to take from him and destroy a mechanical object, perfectly harmless in itself, which he thinks (whether rightly or wrongly makes no difference) is beneficial to him. My conception of the meaning of the Fourth Amendment is, that the citizen alone can unlock the doors to his dwelling, except in the rarest cases, and this is not one of the exceptions. Coke is credited with the maxim that 'An Englishman's home is his castle' (which is morticed into the Fourth Amendment of our National Bill of Rights), and I cannot resist adding the imperishable words by Chatham, of a later English generation:

> The poorest man may, in his cottage, bid defiance to all the forces of the Crown. It may be frail; its roof may shake; the wind may blow through it; the storm may enter; the rain may enter; but the King of England may not enter; all his force dares not cross the threshold of the ruined tenement.

THE RIGHT TO PRESCRIBE FOR ONESELF

"Turning to the other major question in the case, no authority has been shown me that supports the position of the Government, which while admitting the Spectro-Chrome is not inherently dangerous, says in its brief: 'It is claimed to be indirectly dangerous because the ailment of the user is aggravated by reason of the failure to consult competent medical authority.'

"This is admirable frankness on the part of the Government, but, as stated, it is supported by no authority, and I venture that it can be supported by none. I hesitate to labor the point, in opposition to this claim of paternal right, to control the manner in which a person shall seek to cure himself. So many years, generations now, have been devoted to demonstrating that man is often his own best doctor, aside from the question of terrific import of personal liberty involved—it would be but stirring old waters, long calm, to review the successful struggle of healing groups and faiths, unconventional by majority standards.

"More, tremendously more, is here involved—the right of the individual to select his own manner and means of treatment. The question is not, whether false and misleading statements were made to Claimant. The question is, what does he want to do about it? He says 'Nothing,—I am satisfied. I am being helped.' But the Government answers 'We won't allow you to be satisfied. We won't allow you to help yourself. We know that you *may* be led into doing yourself harm, through relying too heavily on this machine, and thus not obtaining proper (by our standards) medical treatment.' Without intending to give offense, I think no such proposition of paternal right in the field of public health has been advanced in modern times. At least I have been unable to find it in encyclopedias, treatises, or law books.

CONCLUSION

"An easy way of disposing of this case would have been to hold that the attempt to stretch the Government's power of seizure and condemnation under the commerce clause to an article in the hands of the ultimate consumer, raised grave constitutional questions which forbade such construction (Federal Trade Commission v. American Tobacco Company, 264 U. S. 298), but I have preferred to meet head-on and to discuss the questions of security of one's dwelling and of personal liberty, which I regard as the true issues in the case. I have done this because I gained the impression during the war, and the impression has been strengthened since hostilities ended, that it is time for Federal judges to dust off the Constitution.

"Judgment will be for the Claimant."

Findings of facts and conclusions of law were filed in accordance with the foregoing opinion, and on August 1, 1946, judgment was entered dismissing the libel and confirming the return of the device and accompanying labeling to the claimant. A notice of appeal to the United States Court of Appeals for the Ninth Circuit was filed on behalf of the Government on August 2, 1946, and on May 15, 1947, the following opinion was handed down by that court:

MATHEWS, *Circuit Judge:* "On a libel of information, appellant, the United States, proceeded against an article called a Spectro-Chrome found in possession

of appellee, William Ray Olsen, in the District of Oregon. Process was issued, and the article was seized. Appellee intervened as claimant of the article, answered the libel and obtained an order directing that the article be returned to him, and it was so returned. Thereafter a trial was had, findings of fact and conclusions of law were stated, and a decree was entered dismissing the libel.[2] From that decree this appeal is prosecuted.

"The proceeding was under § 304 of the Federal Food, Drug and Cosmetic Act, 21 U. S. C. A. § 334, which provides:

(a) Any article of food, drug, device,[3] or cosmetic that is adulterated or misbranded when introduced into or while in interstate commerce * * * shall be liable to be proceeded against while in interstate commerce, or at any time thereafter on libel of information and condemned in any district court of the United States within the jurisdiction of which the article is found: * * *

(b) The article shall be liable to seizure by process pursuant to the libel, and the procedure in cases under this section shall conform as nearly as may be, to the procedure in admiralty; * * *

(d) Any food, drug, device, or cosmetic condemned under this section shall, after entry of the decree, be disposed of by destruction or sale as the court may * * * direct and the proceeds thereof, if sold, less the legal costs and charges, shall be paid into the Treasury of the United States; * * *

Section 502 of the Act, 21 U. S. C. A. § 352, provides:

A drug or device shall be deemed to be misbranded—

(a) If its labeling[4] is false or misleading in any particular.

"These facts are undisputed: The article in question—the so-called Spectro-Chrome—was an instrument, apparatus or contrivance intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease in man and hence was a device, within the meaning of the Act.[5] The article was transported in interstate commerce from Newfield, New Jersey, to Portland, Oregon, in June, 1945. When the article was introduced into and while it was in interstate commerce, its labeling[6] was false and misleading. Hence the article was misbranded, within the meaning of the Act,[7] when introduced into and while in interstate commerce.

"This proceeding was commenced on July 26, 1945. At that time, the article was not in interstate commerce. That, however, is immaterial; for, having been misbranded when introduced into and while in interstate commerce, the article was liable to be proceeded against and condemned at any time thereafter.[8]

"It is immaterial, if true, that appellee had purchased and paid for the article, had it in his home, was satisfied with it and desired to keep it; that the article was not inherently dangerous or harmful; that appellee did not intend to use it commercially or to permit its use by persons other than himself and his mother and brothers, all of whom were over 21 years of age; and that appellee believed that he and his mother had been benefited by its use. Such facts could not and did not exempt the article from the provisions of § 304 of the Act, 21 U. S. C. A. § 334.

"It is said that appellee has a right to prescribe for himself and to 'seek to cure himself of physical ailments by any means he chooses, so long as the means chosen is not inherently dangerous or harmful.'[9] Such a right, if it exists, is subordinate to the rights of appellant under § 304 of the Act, 21 U. S. C. A. § 334.

"There is no merit in the contention that § 304 of the Act, 21 U. S. C. A. § 334, is unconstitutional. The section is constitutional,[10] is applicable to this case

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[2] United States v. One Article of Device Labeled Spectro-Chrome, D. C. Or., 66 F. Supp. 754.

[3] Section 201 (h) of the Act, 21 U. S. C. A. § 321 (h), defines the term "device" as meaning "instruments, apparatus, and contrivances * * * intended (1) for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; or (2) to affect the structure or any function of the body of man or other animals."

[4] Section 201 (m) of the Act, 21 U. S. C. A. § 321 (m), defines the term "labeling" as meaning "all labels and other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article."

[5] See footnote 3.

[6] See footnote 4.

[7] See § 502 of the Act, 21 U. S. C. A. § 352.

[8] See § 304 of the Act, 21 U. S. C. A. § 334.

[9] United States v. One Article of Device Labeled Spectro-Chrome, supra.

[10] United States v. 935 Cases of Tomato Puree, 6 Cir., 136 F. 2d 523; United States v. 62 Packages of Marmola Prescription Tablets, D. C. W. D. Mo., 48 F. Supp. 878, affirmed in 142 F. 2d 107; United States v. Two Bags of Poppy Seeds, 6 Cir., 147 F. 2d 123. See, also, Hipolite Egg Co. v. United States, 220 U. S. 45; McDermott v. Wisconsin, 228 U. S. 115; Seven Cases of Eckman's Alterative v. United States, 239 U. S. 510,

and should be followed. Accordingly, the so-called Spectro-Chrome—the article proceeded against in this case—should be seized and condemned.

"Decree reversed and case remanded for further proceedings in conformity with this opinion."

A petition for certiorari was subsequently filed in the Supreme Court of the United States on behalf of the claimant, and on October 13, 1947, the petition was denied. Thereafter, a petition for an order of seizure was filed by the Government, and on March 15, 1948, the court ordered the device reseized. On March 19, 1948, judgment was entered ordering the condemnation and destruction of the device and its accompanying labeling.

2391. Misbranding of Spectro-Chrome. U. S. v. 1 Device * * * (and 5 other seizure actions). (F. D. C. Nos. 16879, 16900, 16901, 16910, 16915, 16923. Sample Nos. 76872–F, 4061–H, 4175–H, 13743–H, 13887–H, 23316–H.)

LIBELS FILED: On or about July 25, 26, and 30, 1945, Southern District of New York, Northern District of Ohio, Eastern District of Missouri, and District of Delaware.

ALLEGED SHIPMENT: Between the approximate dates of October 13, 1944, and July 9, 1945, from Newfield, N. J., by the Dinshah Spectro-Chrome Institute.

PRODUCT: 6 *Spectro-Chrome* devices at Bronx, N. Y., Cleveland and South Euclid, Ohio, St. Louis County, Mo., and Wilmington, Del. The construction and appearance of each device was essentially the same as the device involved in notices of judgment on drugs and devices, No. 2098.

The devices were accompanied by one or more of the following pieces of printed and graphic matter: "Spectro-Chrome Home Guide," "Favorscope for 1944 [or "1945"]," "Rational Food of Man," "Key to Radiant Health," "Request for Enrollment as Benefit Student," "Auxiliary Benefit Notice—Make Your Own Independent Income as Our Introducer," "Spectro-Chrome General Advice Chart for the Service of Mankind — Free Guidance Request," "Certificate of Benefit Studentship," "Spectro-Chrome—December 1941—Scarlet," "Spectro-Chrome—August 1944 [or "January 1945"]," "Spectro-Chrome—March 1945—Yellow," "Spectro-Chrome in Every Home," and "Spectro-Chrome Metry Encyclopedia."

NATURE OF CHARGE: Misbranding, Section 502 (a), the labeling of the devices contained false and misleading curative and therapeutic claims in substantially the same respect as the device involved in notices of judgment on drugs and devices, No. 2098.

DISPOSITION: August 24, September 5 and 7, and November 21, 1945. Default decrees of condemnation. The devices were ordered delivered to the Food and Drug Administration, for experimental and investigational purposes and for use in other court cases which were pending or which might be filed in the future.

2392. Misbranding of Spectro-Chrome. U. S. v. 1 Device, etc. (F. D. C. No. 16838. Sample No. 4096–H.)

LIBEL FILED: July 19, 1945, Eastern District of Pennsylvania.

ALLEGED SHIPMENT: On or about May 18, 1945, by Dinshah Spectro-Chrome Institute, from Newfield, N. J.

PRODUCT: 1 *Spectro-Chrome* device at Allentown, Pa. The construction and appearance of the device was essentially the same as the device involved in notices of judgment on drugs and devices, No. 2098. The device was accompanied by the following pieces of printed and graphic matter: "Spectro-Chrome Home Guide," "Favorscope for 1945," "Rational Food of Man," "Key to Radiant Health," "Request for Enrollment as Benefit Student," "Auxiliary Benefit Notice — Make Your Own Independent Income as Our Introducer," "Spectro-Chrome General Advice Chart for the Service of Mankind — Free Guidance Request," "Certificate of Benefit Studentship," "Spectro-Chrome — December 1941 — Scarlet," and "Spectro-Chrome — March 1945 — Yellow."

NATURE OF CHARGE: Misbranding, Section 502 (a), the labeling of the device contained false and misleading curative and therapeutic claims in substantially the same respect as the device involved in notices of judgment on drugs and devices, No. 2098.

DISPOSITION: An answer to the libel was filed on August 10, 1945, by La Rue E. Snyder, Allentown, Pa. Thereafter, exceptions to the answer were filed on

behalf of the Government on the ground that the answer contained immaterial, irrelevant, and incompetent statements, and failed to raise any issue with respect to the allegation of misbranding set forth in the libel. Motions were also filed on behalf of the Government, requesting that La Rue E. Snyder be directed to file a claim, post security for cause, and make verification of his answer. On September 8, 1947, upon motion of the United States Attorney and with the consent of counsel for La Rue E. Snyder, an order was entered by the court allowing the Government's exceptions to the answer and granting the Government's motions. It was also ordered that if the order of September 8 were not complied with by La Rue E. Snyder, the Government could appear and move for judgment on the pleadings. On October 27, 1947, the court ordered that the answer be stricken from the record and entered a decree providing for the condemnation and destruction of the device and accompanying labeling.

2393. Misbranding of Spectro-Chrome. U. S. v. 1 Device * * *. (F. D. C. No. 18890. Sample No. 23354–H.)

LIBEL FILED: February 4, 1946, Eastern District of Missouri.

ALLEGED SHIPMENT: On or about October 4, 1945, by Dinshah Spectro-Chrome Institute, from Newfield, N. J.

PRODUCT: 1 *Spectro-Chrome* device at Union, Mo. The construction and appearance of the device was essentially the same as the device involved in notices of judgment on drugs and devices, No. 2098.

The device was accompanied by the following pieces of printed and graphic matter: "Certificate of Benefit Studentship," "Spectro-Chrome General Advice Chart for the Service of Mankind — Free Guidance Request," "Spectro-Chrome Manual for Dinshah Spectro-Chrome," "Favorscope for 1945 for Spectro-Chrome Metry," and "Spectro-Chrome — December 1941 — Scarlet."

NATURE OF CHARGE: Misbranding, Section 502 (a), the labeling of the device bore false and misleading curative and therapeutic claims in substantially the same respect as the device reported in notices of judgment on drugs and devices, No. 2098.

DISPOSITION: Upon refusal of Marie T. Sager and Joseph Sager of Union, Mo., to permit seizure of the device and its labeling which were in their possession, an order to show cause why such parties should not be held in contempt of court was entered on February 21, 1946. Thereafter, answers were filed on behalf of Marie and Joseph Sager, denying that Marie Sager had refused to receive service of the writ of monition under which seizure of the device and its labeling was directed, or that Joseph Sager had refused to allow such seizure. In addition, the answers alleged that the writ of monition was illegally issued and void. After consideration of the evidence and the arguments of counsel, the court, on or about April 1, 1946, handed down findings of fact and conclusions of law to the effect that Marie and Joseph Sager did disobey and resist and did intend to disobey and resist a lawful writ and process of the court, and that such individuals were therefore guilty of contempt. A fine of $100 was imposed against each individual, together with a sentence of 10 days in jail. It was provided, however, that execution of the jail sentence should be stayed upon delivery of the device and its labeling to the marshal. On May 6, 1946, following such delivery of the device and labeling, a default decree of condemnation was entered. It was ordered that the device and the labeling be delivered to the Food and Drug Administration for experimental and investigational purposes, and that they be destroyed when no longer needed for such purposes.

2394. Misbranding of Vapo-Path. U. S. v. Vapo-Path, Inc., and Granville Class. Information dismissed with respect to corporation. Plea of guilty entered with respect to individual; fine of $500 imposed, which was remitted. (F. D. C. No. 21484. Sample Nos. 3000–H, 42606–H, 48101–H, 53208–H.)

INFORMATION FILED: July 22, 1947, Southern District of Ohio, against Vapo-Path, Inc., Dayton, Ohio, and Granville Class, president-treasurer of the corporation.

ALLEGED SHIPMENT: On or about October 29 and November 8, 1945, and February 19 and 21, 1946, from the State of Ohio into the District of Columbia and the States of Kentucky, West Virginia, and Idaho.

PRODUCT: Examination showed that the device consisted of cabinets in which the patient's entire body, except his head, was exposed to warm vapors consisting principally of naphthalene, a coal-tar derivative extensively distributed as moth balls, and accessory pieces in which parts of the body such as a foot,

leg, or arm could be so exposed. The device was attached by means of plumbing fixtures to a type of oven "generator" in which a mixture of naphthalene, with small amounts of other volatile substances and some nonvolatile material, was subjected to heat whereby the warm vapors were transmitted to the device.

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements in leaflets entitled "Be a Millionaire in Your Home Town" and in booklets entitled "Vapo-Path must be Good," which were shipped with the device, were false and misleading. These statements represented and suggested that the device when used as directed would be efficacious in the cure, mitigation, and treatment of arthritis, diabetes, poor elimination, poor circulation, abscess on the lung, continuous cough, sleeplessness, loss of weight, rheumatism, disease of the stomach and kidneys, bad heart conditions, muscular rheumatism, accumulation of poisons in the system, improper elimination, inflammatory rheumatism, nervousness, stiff joints, melancholia, blood poisoning, swelling of eyes, hands, and knees, infection of the sciatic nerve, acidosis, rash, abscesses, high and low temperatures, decay of the jaw bone and sinus, poison in the system, slow kidney action, acid condition, lazy liver, bloating, hay fever, incurable conditions, hopeless conditions, serious physical conditions, and whatever was wrong; that the device when used as directed would be efficacious to straighten out the difficulties with which the human system may be struggling; that it would supply those elements in which the body may be deficient; that it would attack the basic cause of the vast majority of ailments; that it would prevent serious illness and correct improper conditions; that it would be efficacious to keep one fit, buoyant, and in good health; and that it would supply beneficial mineral fumes. The device when used as directed would not be efficacious for the purposes represented.

DISPOSITION: The information against the corporation was dismissed on December 31, 1947, following the filing of a petition in bankruptcy by the corporation on October 22, 1947. In the order of dismissal it was stipulated by the trustee that the machines, oils, minerals, and chemicals used in connection with the machines would not be offered for, or used for, the diagnosis, treatment, or prevention of disease in violation of the law, and that such conditions would be binding on the successor and assigns of the defendant corporation in the event the assets would be sold as a whole at a private sale. On March 16, 1948, a plea of guilty having been entered by Granville Class, the court imposed a fine of $125 on each of the four counts of the information, which fine was remitted.

DRUGS FOR VETERINARY USE*

2395. Alleged misbranding of Sunshine Minerals. U. S. v. Charles J. Korinek (Korinek Laboratories). Plea of guilty. Information ordered dismissed. (F. D. C. No. 12550. Sample Nos. 42690–F, 43068–F, 43069–F.)

INFORMATION FILED: September 7, 1944, Northern District of California, against Charles J. Korinek, trading as Korinek Laboratories, South San Francisco, Calif.

ALLEGED SHIPMENT: On or about June 26, August 30, and September 15, 1943, from the State of California into the State of Oregon.

PRODUCT: Analysis showed that the product consisted essentially of compounds of calcium, iron, magnesium, sodium, potassium, carbonates, phosphates, and sulfates.

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements in accompanying circulars entitled "Better Chicks - More Eggs - More Money," "Guarantee the Health and Livability of Day-Old Poults," "Money-Making Dairies Feed Minerals," "Step up Hog Profits with Sunshine Minerals," and "Successful Sheep Men Are All Feeding Minerals," which circulars were shipped prior to the shipment of the article, were false and misleading, since the article would not fulfill the promises of benefit represented and suggested. The statements represented and suggested that the article would cause the production of better chicks and more eggs and enable the user to make more money and make poultry pay; that it would prevent thin egg shells and make for better shell texture and would increase the thickness and firmness of egg shells; that it would promote maximum growth and development; that it would be efficacious

*See also No. 2373.

to produce strong, sturdy, and uniform development of chicks and pullets, to build up a powerful bodily resistance to the many disorders and diseases affecting poultry, to build stronger bones, muscles, digestive, and other internal organs, to promote a satisfactory development and growth of the nervous system, to greatly reduce malformed breast bones, paralysis, blindness, and roup, and to prevent perosis or slip tendons, and humpbacks; that it would guarantee the health and livability of day-old poults, increase the hatchability and fertility of eggs, produce uniform development of poults, reduce nutritional leg weaknesses, rickets, rubber legs, malformed breasts, bones, blindness, and paralysis; that it would cause production of more milk with less feed and increase the health of cows; that it would keep cows producing profitably for years and would reduce the incidence of nutritional abortion, sterility or nonbreeding, retained after-birth, milk fever, simple garget, red water, and anemia; that it would prevent an unthrifty condition in cattle and prevent them from chewing bones, leather, and wood, or eating dirt; that it would be efficacious to prevent swollen joints and to eliminate goiter (thick neck) in calves, and rickets and various other deformities; that it would reduce scours in calves; that it would be efficacious to assure large, thrifty, well-haired calves that would grow rapidly and would be highly resistant to scours and other disorders; that it would help a cow to develop and drop healthier calves; that it would improve growth, production, and reproduction in cattle; that it would be effective to maintain a mineral reserve in the cow's body equal to the demands made of a dairy cow; that it would be efficacious to reduce breeding trouble, to step up hog profit, and to assure strong, healthy, and vigorous well-haired litters of larger healthier pigs; that it would prevent sagged back, weak pasterns, and small bones in pigs; that it would stop sows from eating their young; that it would be efficacious in the treatment of thumps and paralysis of the hind quarters; that it would prevent rickets and flat feet, spread toes in hogs, and morbid and perverted appetite; that it would satisfy the unnatural craving which makes hogs root; that it would be efficacious to assure strong, healthy, vigorous hogs that carry more pounds of added weight; that it would increase the size and strength of bones and thereby lessen the danger of crippled hogs and broken bones during shipments to distant markets; that it would increase the milk flow of the sow and enrich her milk and body building elements to assure better litters; that it would be efficacious to produce from 20 to 30 pounds greater gain in weight the first six months of the pig's life; that it would prevent milk fever and retained after-birth in sows; that it would reduce paralysis and thumps (anemia) in sows and pigs; that it would increase the flow of sow's milk; that it would be efficacious to cause rapid growth, heavy production, rugged health, and maximum reproduction for all farm animals and poultry; that it would increase the weight of fleece of sheep from 4 percent to 18 percent; that it would be efficacious to cause the growth of strong, sturdy, well-boned sheep; that it would be efficacious to increase the fleece and make it of much better quality, to reduce nutritional abortion, sterility or shy breeding, retained after-birth, suspension of milk in ewes after lambing, heaving pains, and blue bag; that it would be efficacious in overcoming anemia (thumps) in lambs, goiter (big neck), rickets, fragile bones, weak lambs (stiff disease), and dirt and sand eating; that it would be efficacious to cause ewes to have more vitality and to be better breeders, to carry their lambs with less strain on the system, and to produce more milk for the lambs; that it would be efficacious to make lambs more vigorous, stronger, and healthier, and to gain more rapidly and weigh more at maturity; that it would be efficacious to develop stronger bones in lambs; that the article constituted a sure and safe way of preventing lamb troubles, weakened constitution, and general health disorders in the flock; that it would be efficacious to produce larger well-haired fox pups; that it would improve pelts greatly and invigorate the breeding conditions of both males and females; that it would be efficacious to increase production, size, and thrift of litters in rabbits; to prevent the doe from eating the young, and to build up an effective resistance to many disorders common to rabbits; and that it would be efficacious to keep the hairs of dogs in fine condition, to give dogs lots of energy and pep, and to reduce many dog deficiency diseases.

DISPOSITION: September 19, 1944. The defendant entered a plea of guilty. The court ordered the information dismissed, after being informed that evidence had been submitted by the defendant that he had destroyed the literature and had obliterated the reference on the bags to the literature.

2396. Misbranding of Hilltop K–M. U. S. v. 5 Bottles, etc. (and 3 other seizure actions). (F. D. C. Nos. 22689, 23102, 23103, 23112. Sample Nos. 73418–H, 77098–H, 77388–H to 77390–H, incl., 77392–H.)

LIBELS FILED: March 12 and May 6 and 12, 1947, Western District of Wisconsin and Northern District of Iowa.

ALLEGED SHIPMENT: On or about May 23, 1946, and March 31 and April 7 and 23, 1947, from Minneapolis, Minn., by Hilltop Laboratories.

PRODUCT: 78 bottles and 130 jugs of *Hilltop K-M* at Madison and Darlington, Wis., and Clear Lake and Maynard, Iowa. The bottles and jugs were in 1-gallon, half-gallon, and 1-quart sizes. Analysis showed that the product consisted essentially of water with small amounts of potassium dichromate, potassium chlorate, potassium nitrate, epsom salt, and an acid.

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements on the label of the article were false and misleading, since they represented and suggested that the article when used as directed was effective as a tonic and laxative for poultry and was effective as a drinking water antiseptic for poultry; and that the article was effective to kill, in the drinking water of poultry, the pathogenic organisms *Salmonella pullorum*, *Schigella gallinarum*, *Salmonella typhimurium*, and *Pasteurella avicidia*, and thereby treat and prevent the poultry diseases caused by such organisms, namely, pullorum, typhoid, paratyphoid, and cholera. The article would not be effective for such purposes.

DISPOSITION: April 22 and June 3, 18, and 23, 1947. Default decrees of condemnation and destruction.

2397. Misbranding of Hilltop Mor-O. U. S. v. 30 Bottles, etc. (F. D. C. No. 23133. Sample No. 77391–H.)

LIBEL FILED: May 24, 1947, Northern District of Iowa.

ALLEGED SHIPMENT: By Hilltop Laboratories, from Minneapolis, Minn. The product was shipped on or about June 1946, and March 31, 1947, and a number of magazines were shipped on or about April 1, 1947.

PRODUCT: 30 1-quart bottles of *Hilltop Mor-O* at Maynard, Iowa, together with 5 magazines entitled "Hilltop Poultry News," spring issue 1946. Analysis disclosed that the product consisted essentially of water, lactic acid 23.4 percent, tannin extracts, and small amounts of benzoic acid and sodium thiosulfate.

LABEL, IN PART: "Hilltop * * * Liquid Mor-O."

NATURE OF CHARGE: Misbranding, Section 502 (a), the label statements "For Non-Infectious Enteritis * * * Lactic Acid (46%)" and the statement in the magazine "Use Mor-O (Liquid) in poultry drinking water for non-infectious enteritis" were false and misleading, in that such statements represented and suggested that the article when used as directed was effective for the treatment of noninfectious enteritis in poultry, whereas it was not effective for such purpose; and in that poultry raisers could not differentiate between noninfectious enteritis and enteritis due to any infectious agent and would therefore be misled into using the article in the treatment of enteritis in their flocks without due regard to the cause of the enteritis.

DISPOSITION: June 28, 1947. Default decree of condemnation and destruction.

DRUG ACTIONABLE BECAUSE OF OMISSION OF, OR UNSATISFACTORY, INGREDIENTS STATEMENTS*

2398. Misbranding of Ramol (mineral oil). U. S. v. Warren J. Frank and Douglass B. Pew (Frank Pew Oil Co.). Pleas of guilty. Fines of $300 and $600, plus costs, against defendants Frank and Pew, respectively. (F. D. C. No. 23214. Sample No. 49351–H.)

INFORMATION FILED: August 5, 1947, Northern District of Ohio, against Warren J. Frank and Douglass B. Pew, trading as copartners under the name of the Frank Pew Oil Co., Cleveland, Ohio.

ALLEGED SHIPMENT: On or about August 20, 1946, from the State of Ohio into the State of Mississippi.

LABEL, IN PART: "Ramol * * * U. S. P."

NATURE OF CHARGE: Misbranding, Section 502 (e) (1), the article was not designated solely by a name recognized in an official compendium, and its label failed to bear the common or usual name of the drug, i. e., mineral oil.

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*See also Nos. 2359, 2361, 2364, 2378, 2384.

The information covered also a shipment of *Ramol* which was intended for use as a food. This latter shipment was alleged to be misbranded under the provisions of the law applicable to foods.

DISPOSITION: December 19, 1947. Pleas of guilty having been entered, the court imposed fines of $300 and costs against Warren J. Frank and $600 and costs against Douglass B. Pew.

DRUGS ACTIONABLE BECAUSE OF FAILURE TO BEAR AN ACCURATE STATEMENT OF THE QUANTITY OF THE CONTENTS*

2399. Misbranding of Apex Glossatina and Apex Medicated Scalp Cream. U. S. v. The Apex News & Hair Co., Inc., and Archibald J. Morgan. Pleas of guilty. Corporation fined $500; individual sentenced to 1 day in custody of U. S. marshal. (F. D. C. No. 23253. Sample Nos. 5096–H, 11881–H, 66405–H to 66407–H, incl.)

INFORMATION FILED: October 30, 1947, District of New Jersey, against the Apex News & Hair Co., Inc., Atlantic City, N. J., and Archibald J. Morgan, president of the corporation.

ALLEGED SHIPMENT: On or about May 29 and June 13, 1946, and January 14, February 10, and March 14, 1947, from the State of New Jersey into the States of Pennsylvania and Massachusetts.

LABEL, IN PART: "Apex Glossatina Anti Burn Hair and Scalp Ointment * * * Net Contents 4 Ozs." or "Apex Medicated Scalp Cream * * * Net Contents 3 Ozs."

NATURE OF CHARGE: Misbranding, Section 502 (b) (2), the articles failed to bear labels containing accurate statements of the quantity of the contents. (The articles were short-weight.)

DISPOSITION: December 19, 1947. Pleas of guilty having been entered, the court imposed a fine of $500 against the corporation and sentenced the individual to serve one day in the custody of the U. S. marshal.

2400. Misbranding of Apex Glossatina and Apex Medicated Scalp Cream. U. S. v. 21 Dozen Containers, etc. (and 1 other seizure action). (F. D. C. Nos. 22950, 22951. Sample Nos. 66405–H to 66407–H, incl.)

LIBELS FILED: April 18, 1947, Eastern District of Pennsylvania.

ALLEGED SHIPMENT: On or about January 17, February 11, and March 14, 1947, by the Apex News & Hair Co., Inc., from Atlantic City, N. J.

PRODUCT: 37½ dozen metal containers of *Apex Glossatina* and 63 metal containers of *Apex Medicated Scalp Cream* at Philadelphia, Pa.

LABEL, IN PART: "Apex Glossatina Anti Burn Hair and Scalp Ointment * * * Net Contents 4 Ozs." or "Apex Medicated Scalp Cream * * * Net Contents 3 Ozs."

NATURE OF CHARGE: Misbranding, Section 502 (b) (2), the articles failed to bear labels containing accurate statements of the quantity of the contents. (The articles were short-weight.)

DISPOSITION: May 20, 1947. Default decrees of condemnation and destruction.

*See also Nos. 2359, 2360.

INDEX TO NOTICES OF JUDGMENT D. D. N. J. NOS. 2351 TO 2400

PRODUCTS

[11] (2353, 2354, 2374) Permanent injunction issued.
[12] (2355, 2375, 2389) Prosecution contested. Contains opinion of the court.
[13] (2390) Seizure contested. Contains opinion of the court.
[14] (2356) Prosecution contested.

SHIPPERS, MANUFACTURERS, AND DISTRIBUTORS

[11] (2353, 2354, 2374) Permanent injunction issued.
[12] (2355, 2375, 2389) Prosecution contested. Contains opinion of the court.
[13] (2390) Seizure contested. Contains opinion of the court.
[14] (2356) Prosecution contested.

[11] (2353, 2354, 2374) Permanent injunction issued.

U. S. GOVERNMENT PRINTING OFFICE: 1949

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D. D. N. J., F. D. C. 2401–2450 Issued May 1949

FEDERAL SECURITY AGENCY

FOOD AND DRUG ADMINISTRATION

NOTICES OF JUDGMENT UNDER THE FEDERAL FOOD, DRUG, AND COSMETIC ACT

[Given pursuant to section 705 of the Food, Drug, and Cosmetic Act]

2401–2450

DRUGS AND DEVICES

The cases reported herewith were instituted in the United States district courts by the United States attorneys acting upon reports submitted by direction of the Federal Security Administrator.

J. Donald Kingsley, *Acting Administrator, Federal Security Agency.*

Washington, D. C., *November 29, 1948.*

CONTENTS*

DRUGS AND DEVICES ACTIONABLE BECAUSE OF POTENTIAL DANGER WHEN USED ACCORDING TO DIRECTIONS

2401. Misbranding of various formula drugs and androgenic hormone. U. S. v. 9 Cartons, etc. (F. D. C. No. 20272. Sample Nos. 29661–H to 29665–H, incl.)

Libel Filed: June 20, 1946, Northern District of California; amended libel filed June 20, 1947.

Alleged Shipment: The drugs were shipped by Basic Endocrines Sales Co., Inc., from Salt Lake City, Utah, on or about March 5 and 29 and April 10, 1946; and a number of booklets and pamphlets were shipped on or about April 18 and November 13, 1945, from Seattle, Wash., by the National Lithographing Co., at the order of Basic Endocrines Sales Co., Inc.

Product: 9 cartons, each containing 3 packages, of *No. 3 Formula GE–2*, 19 cartons, each containing 3 packages, of *No. 6 Formula GE–5*, 9 cartons, each containing 3 packages, of *No. 14 Formula GH–3F*, 34 cartons, each containing 3 packages, of *No. 23 Formula GH–11*, and 88 cartons of *androgenic hormone* at San Francisco, Calif., together with 106 booklets entitled "Basic Endocrines" and 300 pamphlets entitled "Androgenic Substance in Corn Oil."

Label, in Part: "No. 3 Formula GE–2 30 Capsules Each Capsule contains: (Apoth) Thyroid (U. S. P.) 1/10 gr., Anterior Pituitary (N. F.) 1/3 gr., Ovarian Residue (N. F.) 3 grs., and Vegetable base q. s."; "No. 6 Formula GE–5 30 Capsules Each Capsule contains: (Apoth) Cardiac Substance 5 grs., and Vegetable base q. s."; "No. 14 Formula GH–3F 30 Capsules Each Capsule

*For sale under name of another drug, see No. 2408; failure to bear a label containing the name and place of business of the manufacturer, packer, or distributor, Nos. 2403, 2416.

contains: (Apoth) Thyroid (U. S. P.) ½ gr., Whole Pituitary (N. F.) ¼ gr., Suprarenal Substance (N. F.) ⅔ gr., Ovarian Residue (N. F.) 1½ grs., Placental Substance ½ gr., and Vegetable base q. s."; "No. 23 Formula GH–11 30 Capsules Each Capsule contains: (Apoth) Gastric Mucin 6 grs., Okra 1½ grs."; and "30 Perles No. 105 Androgenic Hormone ½ Capon Unit Per Perle Androgenic Substance derived from testicular tissue dissolved in corn oil."

NATURE OF CHARGE: *No. 3 Formula GE–2.* Misbranding, Section 502 (a), the label statement "Each Capsule contains: (Apoth) Thyroid (U. S. P.) ⅒ gr., Anterior Pituitary (N. F.) ⅓ gr., Ovarian Residue (N. F.) 3 grs. * * * No claim for estrogenic or Progestational activity. Contains no known therapeutically or physiologically active constituent derived from Anterior Pituitary or Ovarian Residue principles, for which recognized methods of assay exist" was misleading since it failed to reveal the material fact that the anterior pituitary and ovarian residue in the article contributed nothing to its therapeutic effects. Further misbranding, Section 502 (a), the statement in the booklet as to the article, "Indications: A rational organotherapy as an auxiliary support in symptoms of hypoovarian, amenorrhea, dysmenorrhea, painful breasts and hot flushes of the menopause," was false and misleading since the article was not effective to fulfill the promises of benefit stated and implied; and, Section 502 (f) (1), the labeling of the article failed to bear adequate directions for use.

No. 6 Formula GE–5. Misbranding, Section 502 (a), the label statement "Each Capsule contains: (Apoth) Cardiac Substance 5 Grs. * * * Contains no known therapeutically or physiologically active constituent derived from cardiac principles for which recognized methods of assay exist" was misleading since it failed to reveal the material fact that the cardiac substance in the article possessed no medicinally useful properties. Further misbranding, Section 502 (a), the statement in the booklet as to the article, "Indications: A rational organotherapy as an auxiliary support in symptoms of muscular weakness of the heart and in some cardiac conditions," was false and misleading since the article was not effective to fulfill the promises of benefit stated and implied; and, Section 502 (f) (1), the labeling of the article failed to bear adequate directions for use.

No. 14 Formula GH–3F. Misbranding, Section 502 (j), the article, by reason of its thyroid content, was dangerous to health when used in the dosage and with the frequency prescribed and recommended in its labeling, i. e., "1 to 3 daily."

No. 23 Formula GH–11. Misbranding, Section 502 (a), the statement "Indications: A rational organotherapy as an auxiliary support in gastro-duodenal ulcerations, inflammations," which statement related to the article and appeared in the booklet, was false and misleading since the article was not effective to fulfill the promises of benefit stated and implied; and, Section 502 (f) (1), the labeling of the article failed to bear adequate directions for use.

Androgenic hormone. Misbranding, Section 502 (a), the label statement "½ Capon Unit Per Perle * * * Androgenic Substance derived from testicular tissue * * * Directions: One to six perles or as indicated" was misleading since it failed to reveal the material facts that ½ capon unit androgenic substance per perle administered in doses of one to six perles is essentially inert; and the following statements relating to the article and appearing in the booklet and pamphlets were false and misleading since the article was not effective to fulfill the promises of benefit stated and implied: (Booklet) "Rationale: Some clinicians have found male sex hormones of value as a replacement therapy in conditions associated with certain types of sexual deficiencies, such as hypogonadism, impotence, under developed genitalia, premature senility, benign prostatic hypertrophy, male climacteric and functional insufficiency" and (pamphlet) "1. Development and maintenance of the prostate, seminal vesicles, spermatogenic elements, the accessory sexual apparatus, including control over the energy with which spermatozoa pass through the various tubes. 2. Secondary male characteristics such as growth and distribution of hair on the head and body. 3. Nervous system. Increases resistance of the central system to fatigue. 4. Stimulation of libido and potency. 5. Control over fat distribution of certain types. 6. Synergism with the female hormone. Indications and Uses. Some clinicians have found male sex hormones of value as a replacement therapy in conditions associated with certain types of sexual deficiencies, such as hypogonadism, impotence, under developed genitalia, premature senility, benign prostatic hypertrophy, male

climacteric and functional insufficiency." Further misbranding, Section 502 (f) (1), the labeling of the article failed to bear adequate directions for use.

DISPOSITION: June 8, 1948. The Basic Endocrines Sales Co., Inc., having been permitted to withdraw its claim in the matter, judgment of condemnation was entered and the products were ordered destroyed.

2402. Misbranding of Electronic Device. U. S. v. 5 * * *. (F. D. C. No. 24176. Sample No. 6216-K.)

LIBEL FILED: January 14, 1948, Western District of Pennsylvania.

ALLEGED SHIPMENT: On or about November 13, 1947, by Saul Brothers, Inc., from Bronx, N. Y.

PRODUCT: 5 Electronic Devices at Pittsburgh, Pa.

LABEL, IN PART: "United Diathermy, Inc., Electronic Device Deluxe Model Serial No. 8408" [or other number] Short Wave Electrodes 27300 KC 115V."

NATURE OF CHARGE: Misbranding, Section 502 (f) (1), the labeling of the device failed to bear adequate directions for use in the treatment of bursitis, arthritis, neuritis, neuralgia, sciatica, common forms of colds, lumbago, and chronic sinus conditions, which were the conditions for which the device was prescribed, recommended, and suggested in its advertising distributed with each device, i. e., a booklet entitled "Good Health brings Long Life and Happiness" disseminated and sponsored by and on behalf of the manufacturer and distributor of the device.

Further misbranding, Section 502 (j), the device was dangerous to health when used in the dosage, and with the frequency and duration prescribed, recommended, and suggested in its labeling, i. e., a leaflet entitled "Instruction Sheet" which was shipped with each device and which contained the following statements: "180 Watt Output 60 Cycle 115 V. A. C. Instruction Sheet Important Read The Following Instructions Carefully Before Using This Apparatus: 1. Place connecting plug into wall socket. 2. Wires of electrode pads to be inserted in Outlets marked 'Electrodes'. 3. Before starting, make certain that: a. Time switch is in zero position; 4. Place electrode pads to the area to be treated, do not cross electrode pad wires. Proper spacing is essential. For example—Place a folded turkish towel between each electrode and the body. 5. Turn time switch to the right to the desired number of minutes. This time switch automatically starts the Short Wave, as you will note by the pilot light in the center of the panel. 6. Turn heat control to the right or to the left until lowest point of meter. Then turn to the right until desired amount of heat is obtained. If too hot turn back to left until you get a comfortable heat. 7. Heat should be comfortably warm—never hot. You will find it far more beneficial to take a longer and milder treatment, than a short treatment that is uncomfortably hot. An uncomfortably hot treatment is wrong and may result in a serious burn. 8. Any metal, in the path of the Short Wave should be avoided. Bed should be non-metallic. If made of metal, cover them up with a heavy mattress. 9. Caution: Unless otherwise instructed by a physician, do not use for: Menstruation or pregnancy Gastric Ulcers Malignant Tumor Acute inflammatory Condition. 10. If any further information is desired, please telephone or write this office."

DISPOSITION: One device was seized, and on February 25, 1948, a default decree of condemnation was entered and the device was ordered destroyed.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF FAILURE TO BEAR ADEQUATE DIRECTIONS OR WARNING STATEMENTS*

2403. Misbranding of estrogenic substances. U. S. v. International Hormones, Inc. Plea of guilty. Fine, $500. (F. D. C. No. 20203. Sample Nos. 30083-H, 30084-H.)

INFORMATION FILED: March 17, 1947, Eastern District of New York, against International Hormones, Inc., Brooklyn, N. Y.

ALLEGED SHIPMENT: On or about May 5 and August 24, 1945, from the State of New York into the State of California.

NATURE OF CHARGE: Misbranding, Section 502 (a), the label statement "Estrogenic Substances in Sesame Oil Consisting of estrone, estradiol, estriol and other ketonic fractions derived from pregnant mares' urine" was false and

*See also Nos. 2401, 2402.

misleading. The statement represented and suggested that the estrogenic material present in the article consisted of estrogens as they naturally occur in and are extracted from pregnant mares' urine, whereas the estrogenic material present in the article did not consist of estrogens as they naturally occur in and are extracted from pregnant mares' urine.

Further misbranding, Section 502 (b) (1), the vials of the article bore no label containing the name and place of business of the manufacturer, packer, or distributor; Section 502 (b) (2), they bore no label containing a statement of the quantity of the contents; Section 502 (e) (2), they bore no label containing the common or usual name of each active ingredient of the article; and, Section 502 (f) (1), the article bore no labeling containing directions for use.

DISPOSITION: June 10, 1948. A plea of guilty having been entered, the court imposed a fine of $500.

2404. Misbranding of Million Dollar Tonic. U. S. v. 212 Bottles * * *. (F. D. C. No. 24198. Sample No. 14105–K.)

LIBEL FILED: January 5, 1948, Northern District of Illinois.

ALLEGED SHIPMENT: On or about November 25, 1947, from Richmond, Ind., by the M. L. Carpenter Medicine Co. of Dublin, Ind.

PRODUCT: 212 bottles of *Million Dollar Tonic* at Chicago, Ill. Examination showed that the product was an aqueous solution of extracts of plant drugs, including aloe, preserved with a small proportion of a salicylate.

NATURE OF CHARGE: Misbranding, Section 502 (a), the label statements "Tonic * * * If taken as an intestinal tonic" were false and misleading as applied to a product which was not capable of exerting a tonic effect upon the human body or of acting as a tonic to the intestines.

Further misbranding, Section 502 (f) (2), the article was essentially a laxative and its labeling failed to bear a warning to the effect that it should not be taken by persons suffering from nausea, vomiting, abdominal pain, or other symptom of appendicitis, and that frequent or continued use of the article or use of the article in accordance with the directions on the label may result in dependence upon laxatives to move the bowels.

DISPOSITION: May 27, 1948. Default decree of condemnation and destruction.

2405. Misbranding of Bush Mulso Tablets, Sulpho, Bush Endo-Veg, Garlic-Parsley Tablets, and Bush Lemo Tabs. U. S. v. 150 Packages, etc. Tried to the court. Judgment for the Government. Decree of condemnation and destruction. (F. D. C. No. 19364. Sample Nos. 35078–H to 35082–H, incl.)

LIBEL FILED: March 18, 1946, Eastern District of Missouri.

ALLEGED SHIPMENT: The *Bush Mulso Tablets* were shipped by the United Health Products Co., from Burbank, Calif., on or about February 18, 1946, and the *Sulpho* was shipped by Paso Robles Lab., from Los Angeles, Calif., on or about February 19, 1946. The other products were shipped by David V. Bush, from Gardena, Calif., on or about February 25, 1946.

PRODUCT: 150 packages of *Bush Mulso Tablets*, 95 bottles of *Sulpho*, 143 packages of *Bush Endo-Veg*, 24 dozen packages of *Garlic-Parsley Tablets*, and 16 dozen packages of *Bush Lemo Tabs* at St. Louis, Mo. The products were being sold in St. Louis by David V. Bush during the course of a series of so-called health lectures at which he offered these products for the treatment of various disease conditions.

LABEL, IN PART: "Bush Mulso Tablets * * * Ingredients: Each tablet contains 6 grains of charcoal and ½ grain of papain combined in an inert base of malt diastase and a vegetable gum binder"; "Sulpho * * * A Concentrate of Sulphur Mineral Hot Springs Water consisting essentially of the Polysulphides and Sulphides of Calcium and Sodium"; "Bush Endo-Veg * * * Ingredients—Each tablet contains Pacific Ocean Kelp as a source of iodine in a base of desiccated alfalfa and celery, with excipients"; "Garlic-Parsley Tablets * * * Each Tablet contains 3 grains of dehydrated Garlic and 3 grains of dehydrated Parsley with sugar, vegetable gums and artificial color as Tablet binders and coating"; and "Bush Lemo Tabs * * * Ingredients—Vitamin C in a base of powdered lemon juice and corn syrup with excipients."

NATURE OF CHARGE: Misbranding, Section 502 (f) (1), the labeling of the articles failed to bear adequate directions for use in those diseases, symptoms, and conditions for which the articles were offered in their advertising disseminated and sponsored by and on behalf of their manufacturer, packer, and

distributor. The *Bush Mulso Tablets* were offered for use in the prevention of neuritis, colitis, and cancer, for aiding vision and digestion, and for pimples, fluttering of the heart, shingles, tonsillitis, and stomach worms. The *Sulpho* was offered for use in the treatment of hemorrhoids, rheumatism, chronic rheumatism, gout, diphtheria, bronchitis, arthritis, and sleeplessness. The *Bush Endo-Veg* was offered for use to keep the thyroid gland and other endocrine glands in condition; to lengthen life; and to prevent flabby muscles, wrinkled face, flat chest, bulging abdomen, hernia, falling arches, varicose veins, double chin, high blood pressure, hardening of the arteries, headache, nausea from liver clogging, acne, skin eruptions, emotional disturbances, ringing in the ears, inferiority complex, menopausal disturbances, liver spots, derangement of the adrenal gland, weakness, stomach sickness, vomiting, abnormal kidney action, goiter, menstrual disorders, arthritis, overweight, watery eyes, and swelling of the feet. The *Garlic-Parsley Tablets* were offered for use in effecting longevity; in preventing calcification; in the treatment of nervous indigestion, cancer, and worms; and for cleansing the blood and eliminating pus from the body. The *Bush Lemo Tabs* were offered for use for pains in the body, driving the toxins of rheumatism and arthritis from the blood, tiredness, loss of appetite, shortness of breath, swelling of the legs, pale skin, bleeding, nosebleed, bleeding of the gums, anemia, ulcer of the stomach, nervousness, diabetes, mental disturbances, pernicious anemia, loss of weight and strength, heart and circulatory conditions, intestinal disorders, and high blood pressure; for keeping the eyes young; and for preventing impairment or loss of vision, loss of elasticity of the veins, colds, tonsillitis, skin blemishes, loosening of teeth, hardening of the arteries, and apoplexy.

DISPOSITION: David V. Bush of Mehoopany, Pa., appeared as claimant on or about April 8, 1946, and filed an answer denying that the products were misbranded as alleged in the libel. Thereafter, an application to intervene was filed on behalf of the National Dietary Food Association; and after a hearing in the matter the court, on or about February 3, 1947, ruled that the association should be permitted to intervene solely for the purpose of filing a memorandum in the case. A stipulation of facts which was agreed to by the Government and the claimant was filed on February 3, 1947. After consideration of the facts of the case and the briefs of the parties, the court, on July 11, 1947, handed down the following findings of fact and conclusions of law:

MOORE, *District Judge:*

FINDINGS OF FACT

"1. That the Marshal of this District, pursuant to Libel of Information filed in this cause, did, on March 20, 1946, seize:

67 packages of 'BUSH MULSO TABLETS,'
36 bottles of 'SULPHO,'
60 packages of 'BUSH ENDO-VEG,'
12 dozen packages of 'GARLIC-PARSLEY TABLETS,'
8 dozen packages of 'BUSH LEMO TABS,'

in the possession of David V. Bush at 2626 South Grand, St. Louis, Missouri, within the Eastern Division of Eastern Judicial District of Missouri.

"2. That the Marshal of this District did, on March 20, 1946, serve a copy of the said libel on David V. Bush, 2626 South Grand, St. Louis, Missouri, in whose possession the articles seized were found.

"3. That David V. Bush did file a verified claim of ownership to the articles seized in the cause herein.

"4. That the Claimant, David V. Bush, did file an Answer in the cause herein.

"5. That all of the said articles seized in the cause herein were shipped in interstate commerce from the State of California to St. Louis, in the State of Missouri.

"6. That David V. Bush was the packer and the distributor of the said articles of drug seized herein.

"7. That all of said articles seized herein were intended for use in the cure, mitigation, treatment, or prevention of disease in man or intended to affect the structure or function of the body of man and are, therefore, articles of drug under the Food, Drug and Cosmetic Act.

"8. That the label which appeared on the article of drug labeled in part 'Bush Mulso Tablets,' Libelant's Exhibit 1, was the label which appeared on each package of the said article of drug at the time that said drug was shipped in interstate commerce from Los Angeles, California, to St. Louis, Missouri, via Railway Express Agency, on or about February 19, 1946, and at the time that the said article of drug was seized in the cause herein.

"9. That the label on the individual packages of the article of drug labeled in part 'Bush Mulso Tablets' contains the statement: 'Directions: Three to six tablets after meals as required,' and the further statement: 'Provides the adsorbing properties of charcoal with the proteolytic enzymes or papain.'

"10. That there is no statement on the label of any disease or condition in man, or of the structure or other function of the body of man, informing the consumer when the directions 'Three to six tablets after meals as required' are to be followed.

"11. That the statement: 'Provides the adsorbing properties of charcoal with the proteolytic enzymes of papain' and the statement of the contents of the said article of drug, which also appears on the said label, do not inform the consumer of the use of the article of drug in the diagnosis, cure, mitigation, treatment, or prevention of any disease in man or the effect of the said article of drug upon any structure or any function of the body of man, or of any other use for the said article of drug.

"12. That the statement: 'Directions: Three to six tablets after meals as required,' suggests to the consumer that the said article of drug is intended to be used in the diagnosis, cure, mitigation, treatment, or prevention of some disease in man, or to have an effect upon some structure or some function of the body of man, but standing without a further statement as to its intended use, is misleading.

"13. That directions for use contained upon the label upon each package of the article of drug labeled in part 'Bush Mulso Tablets,' Libelant's Exhibit 1, are not adequate and do not inform the consumer of any use of the said drug.

"14. The label is misleading in view of the representation: 'Directions: Three to six tablets after meals as required,' in that it does not contain any statement as to the disease or condition in man or of the effect on the structure or body function for which the directions 'three to six tablets as required' are to be followed.

[Findings 15 to 27, inclusive, relate to "Bush Sulpho" and "Bush Endo-Veg" and are generally similar to those in paragraphs 8 to 14, inclusive, with reference to "Bush Mulso Tablets."]

"28. That the said label, which appeared on the article of drug, labeled in part 'GARLIC-PARSLEY TABLETS,' Libelant's Exhibit 4, was the label, which appeared on each package of the said article of drug at the time that the said article was shipped in interstate commerce from Gardena, California, to St. Louis, Missouri, via Railway Express Agency, on or about February 25th, 1946, and at the time that the said article of drug was seized in the cause herein.

"29. That the label on the individual packages of the article of drug labeled in part 'GARLIC-PARSLEY TABLETS,' Libelant's Exhibit 4, contains the statement 'Each Tablet contains 3 grains of dehydrated Garlic and 3 grains of dehydrated Parsley with sugar, vegetable gums and artificial color as Tablet binders and coating. Suggested Use: For those persons wishing to include garlic and parsley in the regular diet, two of these tablets taken three times a day offers a convenient easy method. (No evidence of physiologic or therapeutic value.).'

"30. That there is no statement on the label of any disease or condition of man or of the structure or other functions of the body, for which the said article of drug is recommended as a diagnosis, cure, mitigation or treatment so as to inform the consumer when the directions 'two of these tablets taken three times a day' are to be followed.

"31. That the statement 'For those persons wishing to include garlic and parsley in the regular diet' does not inform the consumer of the said article of drug in the diagnosis, cure, mitigation or prevention of any disease in man or the effect of the said article of drug upon any structure or any function of the body of man or of any other use for the said article of drug.

"32. That as the said article is an article of drug, the said statement 'No evidence of physiologic or therapeutic value,' which may have been intended by the shipper to avoid the effect of the Food, Drug and Cosmetic Act, only

gives the consumer information that the said article has no use rather than states its intended use.

"33. That the statement of the 'Suggested Use' suggests to the consumer that the said article of drug is intended to be used in the diagnosis, cure, mitigation, treatment or prevention of some disease in man or to have an effect upon some structure or some function of the body of man, but standing without further statement as to its intended use is not adequate directions for use and is misleading.

"34. That the directions for use contained on the label upon each package of the article labeled in part 'GARLIC-PARSLEY TABLETS,' Libelant's Exhibit 4, do not inform the consumer of the use of said drug and therefore are not adequate directions for use.

"35. That the label is misleading and does not contain adequate directions for use in view of the representation 'Suggested Use: For those persons wishing to include garlic and parsley in the regular diet, two of these tablets taken three times a day, offers a convenient easy method.' in that it does not contain any statement as to the disease or condition in man or the effect upon the structure or any function of the body of man for which the said article of drug is a diagnosis, cure, mitigation or treatment, and for which two of these tablets three times a day are to be followed.

"36. That the said label, which appeared on the article of drug 'BUSH LEMO TABS,' Libelant's Exhibit 5, was the label, which appeared on each package of the article of drug at the time that said article of drug was shipped in interstate commerce from Gardena, California, to St. Louis, Missouri, via Railway Express Agency on or about February 25th, 1946, and at the time that the said article of drug was seized in the cause herein; that the label on the individual packages of the article of drug labeled in part 'BUSH LEMO TABS' contains the statement 'A SPECIAL DIETARY SOURCE OF VITAMIN C SUGGESTED USE—One to two tablets daily. Tablets may be chewed or swallowed with water. Each tablet provides the adult with the minimum daily requirements of Vitamin C and the child with 1½ times the minimum requirements.'; that there is no statement on the label of any disease or condition in man or the structure or other function of the body of man for which the said article of drug is a diagnosis, cure, mitigation or treatment, so as to inform the consumer when the directions 'One to two tablets daily' are to be followed.

"37. That the statement 'A SPECIAL DIETARY SOURCE OF VITAMIN C' and 'Each tablet provides the adult with the minimum daily requirements of Vitamin C and the child with 1½ times the minimum requirements' do not inform the consumer of the use of the said article of drug in the diagnosis, cure, mitigation, treatment or prevention of any disease in man, or the effect of the said article of drug upon any structure or any function of the body of man or any other use for the said article of drug.

"38. That the statement 'SUGGESTED USE—One to two tablets daily' suggest to the consumer that the said article of drug is intended to be used in the diagnosis, cure, mitigation, treatment or prevention of any disease in man or to have an effect upon some structure or some function of the body of man, but standing without any further statement as to its intended use, the said label does not contain adequate directions for use and is misleading.

"39. That the directions for use contained upon said label upon each package of the drug labeled in part 'BUSH LEMO TABS,' Libelant's Exhibit 5, do not inform the consumer of any use of the said drug and are therefore inadequate directions for use.

"40. That the label does not contain adequate directions for use and is misleading in view of the representation 'SUGGESTED USE—One to two tablets daily,' and that the said label does not contain any statement of the disease or condition in man or the effect upon the structure or body function for which the directions 'One to two tablets daily' are to be followed.

CONCLUSIONS OF LAW

"1. That each of the said articles of drug were introduced into and were shipped in interstate commerce from California to St. Louis, Missouri.

"2. That the said articles of drug, seized in the cause herein, were intended for use in the cure, mitigation, treatment or prevention of the disease in man, or intended to affect the structure or function of the body of man, and are therefore articles of drug under the Federal Food, Drug and Cosmetic Act of 1938, as amended (21 U. S. C. A. 321 (g)).

"3. A drug is misbranded unless its labeling bears 'adequate directions for use' (21 U. S. C. A., Section 352 (f)).

"4. The requirement that the labeling bear 'adequate directions for use' requires not only that the labeling bear statement of the dosage or the amount, which is recommended that the consumer use, but also a statement of the purpose, namely, the disease or the effect upon the structure or function of the body for which the article of drug is to be taken.

"5. That directions for use are not adequate unless the purpose for which the drug is to be taken, as well as the amount to be taken, appear on the labeling.

"6. That the labels on the five articles of drug seized herein do not bear a statement of the disease or of the effect on the structure or function of the body of man, for which the said articles of drug are to be used, and therefore the labeling does not bear adequate directions for use.

"7. That the labeling is misleading.

"8. That the said articles of drug seized herein are misbranded.

"9. That the said articles of drug seized herein are subject to forfeiture and condemnation to the United States.

"10. Because of the facts heretofore found, libelant is entitled to a decree of condemnation and forfeiture.

"11. That the articles of drug seized herein were seized in the Eastern Judicial District, Eastern Division, of Missouri, and that the Court has jurisdiction over this cause by virtue of Section 334, Title 21, U. S. C. A.

"12. That as no showing has been made that the said articles of drug seized herein have any value or can be sold without violating the Federal Food, Drug and Cosmetic Act, and any State or local law, the said articles of drug shall be destroyed by the United States Marshal.

"13. Libelant is entitled to its costs herein.

"14. Under the facts heretofore found and the law, it is not necessary to pass upon the validity of the regulation, 2.106a1, of the Administrator of the Food and Drug Administration, or to make any findings of fact as to the advertising disseminated by the claimant herein, or to determine the customary conditions of purchase and use of the said articles of drug."

In accordance with the above findings and conclusions, a decree was entered on July 11, 1947, forfeiting the products to the United States and directing that they be destroyed. On July 21, 1947, the claimant filed a motion for a new trial and to amend the findings of fact and conclusions of law. After considering the briefs of the parties, the court, on March 23, 1948, overruled the claimant's motion for a new trial; and on August 4, 1948, the court ordered that the decree for destruction of the products be executed.

2406. Misbranding of pile pipes. U. S. v. 702 * * *. (F. D. C. No. 24347. Sample No. 26662–K.)

LIBEL FILED: February 17, 1948, Eastern District of Missouri.

ALLEGED SHIPMENT: On or about July 18, 1946, by the Victor Metal Products Corp., from Brooklyn, N. Y.

PRODUCT: 702 *pile pipes* at St. Louis, Mo. Examination showed that the pipes were plastic tubes which were threaded at one end to attach to collapsible tubes of ointment.

NATURE OF CHARGE: Misbranding, Section 502 (f) (1), the labeling of the article failed to bear adequate directions for use.

DISPOSITION: March 18, 1948. Default decree of condemnation and destruction.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF DEVIATION FROM OFFICIAL OR OWN STANDARDS

2407. Adulteration and misbranding of Gaduplex and Vibeta Elixir with Iron. U. S. v. Columbus Pharmacal Co., Freeman A. Rostofer, and Robert N. Fullerton. Pleas of guilty. Fine of $600 against each defendant. (F. D. C. No. 24267. Sample Nos. 53833–H, 83283–H.)

INFORMATION FILED. June 15, 1948, Southern District of Ohio, against the Columbus Pharmacal Co., a corporation, Columbus, Ohio, and Freeman A. Rostofer, president, and Robert N. Fullerton, vice-president.

ALLEGED SHIPMENT: On or about December 18, 1946, and July 14, 1947, from the State of Ohio into the State of Kentucky.

NATURE OF CHARGE: *Gaduplex.* Adulteration, Section 501 (c), the strength of the article differed from that which it was represented to possess, since each fluid ounce of the article was represented to supply approximately 4.5 milligrams of vitamin B_1, equivalent to 1,500 International Units of vitamin B_1, and to supply approximately 60 milligrams of niacin, whereas each fluid ounce of the article supplied a lesser amount of vitamin B_1 and niacin. Misbranding, Section 502 (a), the label statement "Each Fluidounce Supplies Approximately * * * Vitamin B_1 (Thiamin) (1,500 I. U.) 4.5 mg. * * * Niacin . . . 60.0 mg." was false and misleading.

Vibeta Elixir with Iron. Adulteration, Section 501 (c), the strength of the article differed from that which it was represented to possess, since each fluid ounce of the article was represented to contain 3 milligrams of vitamin B_1, equivalent to 1,000 International Units of vitamin B_1, whereas each fluid ounce of the article contained a lesser amount of vitamin B_1. Misbranding, Section 502 (a), the label statement "Each Fluidounce Represents * * * Vitamin B_1 . . . (1,000 I. U.) 3 mg." was false and misleading.

DISPOSITION: June 18, 1948. Pleas of guilty having been entered, the court imposed a fine of $600 against each defendant.

2408. Adulteration and misbranding of estrogenic substance. U. S. v. Halfdan Hebo. Plea of not guilty. Tried to the jury; verdict of guilty. Fine of $500 on count 1; imposition of sentence suspended on count 2; defendant placed on probation for 2 years. (F. D. C. No. 17816. Sample No. 54877–F.)

INFORMATION FILED: January 30, 1947, Southern District of New York, against Halfdan Hebo, New York, N. Y.

ALLEGED SHIPMENT: On or about September 11, 1944, from the State of New York into the State of Wisconsin.

NATURE OF CHARGE: Adulteration, Section 501 (d) (2), an inert compound, cholesterol, had been substituted in part for estrogenic substance.

Misbranding, Section 502 (e) (2), the article was fabricated from two or more ingredients and its label did not bear the common or usual name of each active ingredient; and, Section 502 (i) (3), it was offered for sale under the name of another drug, in that it was offered for sale under the name "Estrogenic Substance From Pregnant Mares' Urine."

DISPOSITION: March 6, 1947. A plea of not guilty having been entered, the case came on for trial before a jury. At the conclusion of the trial, the jury returned a verdict of guilty. Thereupon, the court imposed a fine of $500 on count 1 of the information relating to the adulteration of the product, suspended the imposition of sentence on count 2 relating to the charge of misbranding, and placed the defendant on probation for 2 years.

2409. Adulteration and misbranding of estrogenic substance in sesame oil and misbranding of estrogenic substance powder. U. S. v. Hema Drug Co., Inc. Plea of guilty. Fine, $525. (F. D. C. No. 16572. Sample Nos. 85231–F, 31201–H.)

INFORMATION FILED: March 27, 1946, Eastern District of New York, against the Hema Drug Co., Inc., Maspeth, N. Y.

ALLEGED SHIPMENT: On or about November 27, 1944, from the State of New York into the States of California and Pennsylvania.

LABEL, IN PART: "Estrogenic Substance Powder," or "Estrogenic Substance In Sesame Oil." The latter was invoiced as "Natural Estrogenic Hormone in Sesame Oil."

NATURE OF CHARGE: *Estrogenic substance in sesame oil.* Adulteration, Section 501 (d), substances other than natural estrogenic hormone in sesame oil had been substituted in whole or in part for natural estrogenic hormone in sesame oil, which the article was represented to be.

Both products. Misbranding, Section 502 (e) (2), the articles were not designated solely by names recognized in an official compendium and were fabricated from two or more ingredients, and the labels failed to bear the common or usual name of each active ingredient of the articles.

DISPOSITION: July 8, 1948. A plea of guilty having been entered, the court imposed a fine of $175 on each of the 3 counts of the information.

2410. Adulteration of physiological solution of sodium chloride and distilled water and adulteration and misbranding of Dolamin, Cal-G-Sol, and sodium salicylate and iodide with colchicine. U. S. v. Harvey Laboratories, Inc., and Aaron Lichtin. Pleas of nolo contendere. Fine of $300 against each defendant. (F. D. C. No. 24225. Sample Nos. 40298-H, 54292-H, 66147-H, 73688-H, 87641-H, 87643-H, 87646-H, 87647-H.)

INDICTMENT RETURNED: March 5, 1948, Eastern District of Pennsylvania, against Harvey Laboratories, Inc., Philadelphia, Pa., and Aaron Lichtin, treasurer of the corporation.

ALLEGED SHIPMENT: Between the approximate dates of January 2 and April 11, 1947, from the State of Pennsylvania into the States of Florida, New Jersey, Ohio, and New York.

NATURE OF CHARGE: *Dolamin.* Adulteration, Section 501 (c), the purity and quality of the article fell below that which it purported and was represented to possess, in that it purported and was represented to be of a purity and quality suitable and appropriate for parenteral use, whereas it was not of such purity and quality since it contained undissolved material. Misbranding, Section 502 (a), the label statement "For local and perineural infiltration" was false and misleading in that it represented and suggested that the article would be suitable and appropriate for parenteral use, whereas it would not be suitable and appropriate for such use since it contained undissolved material.

Physiological solution of sodium chloride. Adulteration, Section 501 (b), the article purported to be and was represented as "Physiological Solution of Sodium Chloride," a drug the name of which is recognized in the United States Pharmacopoeia, but its quality and purity fell below the official standard. The standard provides that unless specified for use other than parenteral use, the drug must conform to the requirements for injections prescribed in the Pharmacopoeia. The article was not specified for use other than parenteral use and it failed to meet the requirements for injections, since it was not substantially free of undissolved material; and its difference in quality and purity from the standard was not plainly stated, or stated at all, on its label. Further adulteration, Section 501 (d) (2), phenol had been substituted in part for "Physiological Solution of Sodium Chloride," in that the specifications for physiological solution of sodium chloride, which are set forth in the United States Pharmacopoeia, do not provide for the inclusion of phenol, and the article contained phenol.

Distilled water. Adulteration, Section 501 (b), the article purported to be "Water for Injection," a drug the name of which is recognized in the United States Pharmacopoeia, but its quality and purity fell below the official standard since it contained undissolved material which could be detected readily when tested in accordance with the prescribed method; and the difference in quality and purity of the article from the official standard was not plainly stated, or stated at all, on the label.

Sodium salicylate and iodide with colchicine. Adulteration, Section 501 (b), the article purported to be and was represented as "Ampuls of Sodium Salicylate and Iodide with Colchicine," a drug the name of which is recognized in the National Formulary, but its quality and purity fell below the official standard since it contained undissolved material that was readily discernible by the unaided eye when viewed in accordance with the prescribed method; and its difference in quality and purity from the standard was not plainly stated, or stated at all, on its label. Misbranding, Section 502 (a), the label statement "For Intravenous Use" was false and misleading, in that the article was not suitable and appropriate for intravenous use since it contained undissolved material.

Cal-G-Sol. Adulteration, Section 501 (c), the purity and quality of the article fell below that which it purported and was represented to possess, in that it purported and was represented to be of a purity and quality suitable and appropriate for intravenous and intramuscular use, whereas it was not of such purity and quality since it contained undissolved material. Misbranding, Section 502 (a), the label statement "For Intravenous or Intramuscular use" was false and misleading.

DISPOSITION: June 22, 1948. Pleas of guilty having been entered, the court imposed a fine of $300 against each defendant.

2411. Adulteration of isotonic solution of sodium chloride. U. S. v. 188 Vials * * *. (F. D. C. No. 24597. Sample No. 31134–K.)

LIBEL FILED: April 15, 1948, Southern District of California.

ALLEGED SHIPMENT: On or about March 19, 1948, by Bristol Laboratories, Inc., from Syracuse, N. Y.

PRODUCT: 188 20-cc. size vials of *isotonic solution of sodium chloride* at Los Angeles, Calif.

NATURE OF CHARGE: Adulteration, Section 501 (b), the article purported to be and was represented as "Isotonic Sodium Chloride Solution for Parenteral Use," a drug the name of which is recognized in the United States Pharmacopoeia, and its quality and purity fell below the official standard since it was contaminated with undissolved material.

DISPOSITION: May 19, 1948. Default decree of condemnation and destruction.

2412. Adulteration and misbranding of sulfathiazole tablets. U. S. v. 23 Bottles * * *. (F. D. C. No. 24374. Sample No. 8268–K.)

LIBEL FILED: March 11, 1948, District of New Jersey.

ALLEGED SHIPMENT: On or about February 4, 1948, by the Ziegler Pharmacal Co., from Buffalo, N. Y.

PRODUCT: 23 bottles of *sulfathiazole tablets* at Newark, N. J. Examination showed that each bottle contained approximately 850 whole tablets and broken pieces of approximately 150 tablets. Approximately 380 whole tablets contained less than 0.475 gram of sulfathiazole.

LABEL, IN PART: "1000 Tablets Sulfathiazole Each Tablet contains 0.5 gm. 2-Sulfanilylaminothiazole."

NATURE OF CHARGE: Adulteration, Section 501 (b), the article purported to be and was represented as "Sulfathiazole Tablets," a drug the name of which is recognized in the United States Pharmacopoeia, and its strength differed from the official standard since the article consisted of tablets of less than 95 percent of the declared amount of sulfathiazole.

Misbranding, Section 502 (a), the label statement "1000 Tablets" was false and misleading as applied to an article which contained in each bottle many broken pieces of tablets.

DISPOSITION: May 11, 1948. Default decree of condemnation and destruction.

2413. Adulteration of catnip. U. S. v. 2 Bales * * *. (F. D. C. No. 24401. Sample No. 27147–K.)

LIBEL FILED: January 8, 1948, Southern District of Illinois.

ALLEGED SHIPMENT: On or about April 4, 1946, by the Wilcox Drug Co., of Boone, N. C., from Elk Park, N. C.

PRODUCT: 2 150-pound bales of *catnip* at Peoria, Ill. Examination showed that not less than 25 percent of the stems of the product were over 4 millimeters in diameter.

NATURE OF CHARGE: Adulteration, Section 501 (b), the quality of the product fell below the official standard, since the National Formulary provides that not more than 5 percent of the stems of *catnip* shall be over 4 millimeters in diameter.

DISPOSITION: June 24, 1948. Default decree of condemnation and destruction.

2414. Adulteration and misbranding of prophylactics. U. S. v. 13 Cartons, etc. (and 1 other seizure action). (F. D. C. Nos. 24337, 24694. Sample Nos. 667–K, 10205–K, 10206–K.)

LIBELS FILED: On or about February 11 and April 5, 1948, Southern District of New York and Northern District of Georgia.

ALLEGED SHIPMENT: On or about December 31, 1947, and January 7 and February 19, 1948, by the Duratex Corp., from Newark, N. J.

PRODUCT: *Prophylactics.* 13 cartons containing approximately 1,000 gross and 7 cartons containing approximately 500 gross at New York, N. Y., and 86 gross at Atlanta, Ga. Examination of samples disclosed that 26 percent of the 13-carton lot, 8 percent of the 7-carton lot, and 2.87 percent of the 86-gross lot, were defective by reason of the presence of holes.

LABEL, IN PART: (Atlanta lot) "Fan Genuine Latex Prophylactics."

NATURE OF CHARGE: Adulteration, Section 501 (c), the quality of the article fell below that which it purported and was represented to possess.

Misbranding, Section 502 (a), the statement "Prophylactics" on the label of the article in the Atlanta lot was false and misleading as applied to an article containing holes.

DISPOSITION: March 10 and May 13, 1948. Default decree of condemnation and destruction.

2415. Adulteration and misbranding of prophylactics. U. S. v. 48 Gross * * *. (F. D. C. No. 24372. Sample No. 442–K.)

LIBEL FILED: March 11, 1948, Western District of North Carolina.

ALLEGED SHIPMENT: On or about January 29, 1948, by W. H. Reed & Co., Inc., from Atlanta, Ga.

PRODUCT: 48 gross of *prophylactics* at Shelby, N. C. Examination of samples showed that 5 percent were defective in that they contained holes.

LABEL, IN PART: "P A N Tested Prophylactics."

NATURE OF CHARGE: Adulteration, Section 501 (c), the quality of the article fell below that which it purported and was represented to possess.

Misbranding, Section 502 (a), the label statement "Tested Prophylactics" was false and misleading as applied to an article containing holes.

DISPOSITION: May 17, 1948. W. H. Reed & Co., Inc., claimant, having consented to the entry of a decree, judgment of condemnation was entered and the product was ordered released under bond for segregation and conversion of the unfit portion into scrap rubber, under the supervision of the Federal Security Agency. The product was found unmarketable and was converted into scrap rubber and burned.

2416. Adulteration and misbranding of clinical thermometers. U. S. v. 16 Dozen * * *. (F. D. C. No. 24375. Sample No. 32384–K.)

LIBEL FILED: March 11, 1948, Northern District of California.

ALLEGED SHIPMENT: On or about January 30, 1948, by the Philbern Thermometer Co., from New York, N. Y.

PRODUCT: 16 dozen envelopes each containing 1 *clinical thermometer* at San Francisco, Calif. Examination of 24 thermometers showed that 11 would not give accurate readings.

NATURE OF CHARGE: Adulteration, Section 501 (c), the quality of the article fell below that which it purported and was represented to possess, since it would not give accurate readings.

Misbranding, Section 502 (a), the following label statements were false and misleading as applied to an article that would not give accurate readings: "This certifies that this thermometer has been tested on this date at 96°, 100°, 104° and 106° Fahrenheit scale or its equivalent in Centigrade scale, and is correct within plus or minus 2/10 at any of these points. This test is governed by a standard thermometer which has been tested and approved by the Bureau of Standards, Washington, D. C. This thermometer is guaranteed to be of absolute accuracy." Further misbranding, Section 502 (b) (1), the article failed to bear a label containing the name and place of business of the manufacturer, packer, or distributor.

DISPOSITION: September 21, 1948. Default decree of condemnation and destruction.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF FALSE AND MISLEADING CLAIMS

DRUGS FOR HUMAN USE*

2417. Action to enjoin and restrain the interstate shipment of Dr. Hartman's Modified Diabetic Treatment. U. S. v. Dr. Perry Vernon Hartman, Sr. (Hartman Diabetic Hospital). Consent decree granting injunction. (Inj. No. 184.)

COMPLAINT FILED: May 26, 1948, Southern District of Illinois, against Dr. Perry Vernon Hartman, Sr., trading as Hartman Diabetic Hospital at Granville, Ill.

NATURE OF CHARGE: That the defendant had been and was causing to be introduced and delivered for introduction into interstate commerce at Spring Valley,

*See also Nos. 2401, 2403, 2404, 2407, 2410, 2412, 2414–2416.

Ill., and other places within the jurisdiction of the court, an article of drug which he manufactured and packed, and which consisted of a bottle of liquid prepared from vinegar, potassium nitrate, and alcohol, and a package of tablets containing pepsin and pancreatin. The bottle of liquid was labeled "The Hartman Diabetic Hospital Granville, Illinois P. V. Hartman, Sr., M. D. Reg. No. 1778 _____, 194__ For _____ Address _____ Dr. Hartman's Modified Diabetic Treatment —Always Shake Well— Take one tablespoon full in ½ glass of water, add juice of ½ orange and sip with your meals. Be sure to take three tablets before each meal. Avoid sugars and starches. Walk twice every day, two or three miles if possible." The package of tablets was labeled "The Hartman Clinic Granville Illinois * * * Directions: Take three tablets with each meal." A booklet entitled "A Brochure on Diabetes," and containing a discussion of the cause of diabetes and an outline of the method of treatment by Dr. Perry Vernon Hartman, Sr., accompanied the article of drug as labeling. The article of drug was charged to be misbranded under Section 502 (a), in that the statements in its labeling which represented and suggested that it would be efficacious in the cure, mitigation, and treatment of diabetes, were false and misleading since it would not be efficacious for such purposes.

Prayer of Complaint: That the defendant be restrained and enjoined during the pendency of the action, and permanently, from commission of the acts complained of.

Disposition: May 26, 1948. The defendant having admitted the facts charged in the complaint, and having consented to the entry of a decree, the court entered an order enjoining the defendant from directly or indirectly introducing or delivering for introduction into interstate commerce, in violation of Section 301 (a) of the Act, the article of drug or any like or similar preparation similarly labeled and misbranded. It was ordered also that at the request of an officer or employee designated by the Federal Security Administrator, the defendant should permit such officer or employee at reasonable times to have access to, and to copy all records showing the movement in interstate commerce of, the article of drug or any similar preparation, and the quantity, the shipper, and the consignee thereof.

2418. Misbranding of Lin-A-Cea. U. S. v. Parke D. Brollier (Park-Lee Products Co.). Plea of nolo contendere. Fine, $300 and costs. (F. D. C. No. 23242. Sample No. 38406–H.)

Indictment Returned: February 16, 1948, Northern District of Ohio, against Parke D. Brollier, trading as Park-Lee Products Co., Lorain, Ohio.

Alleged Shipment: Or or about August 22, 1946, from the State of Ohio into the State of Michigan.

Product: Examination showed that the product was ground, roasted flaxseed.

Nature of Charge: Misbranding, Section 502 (a), the label statements, "due to the high percentage of Linoleic, Linolenic Acids, one or two heaping teaspoonfuls three or four times a day is usually sufficient. * * * The important Amino Acids Cystine Methionine Arginine Histidine Lysine Tyrosine Tryptophane Phenylalanine Threonine Leucine Valine Isoleucine * * * The Amino, Linoleic, Linolenic Acids are Nutritionally Essential," and certain statements appearing in a circular entitled "Lin-A-Cea," which was enclosed in the package containing the article, were false and misleading. These statements represented and suggested that the amino acid and linoleic and linolenic acids content of the article was significantly different from that found in the ordinary diet; that the article would furnish nutritional elements which are not readily supplied by the ordinary diet; that the amino acids and linoleic acids are usually lacking in the ordinary diet; and that the article would be efficacious in the cure, mitigation, and treatment of fatigue, indigestion, high blood pressure, asthma, sinus trouble, painful movement of the joints, eczema, and lack of resistance to disease. The amino acid and linoleic and linolenic acids content of the article was not significantly different from that found in the ordinary diet; the article would furnish no nutritional elements which are not readily supplied by the ordinary diet; the amino acids and linoleic and linolenic acids are not usually lacking in the ordinary diet; and the article would not be efficacious in the cure, mitigation, and treatment of the above-mentioned disease conditions.

The article was alleged also to be misbranded under the provisions of the law applicable to foods, as reported in notices of judgment on foods.

DISPOSITION: May 10, 1948. A plea of nolo contendere having been entered, the court imposed a fine of $300 and costs.

2419. Alleged misbranding of Protecto. U. S. v. Bess J. Levine (Miracle Food Co.). Plea of not guilty. Tried to the court. Verdict of not guilty. (F. D. C. No. 23588. Sample No. 41022–H.)

INFORMATION FILED: February 13, 1948, Eastern District of Pennsylvania, against Bess J. Levine, trading as the Miracle Food Co., Philadelphia, Pa.

ALLEGED SHIPMENT: On or about January 31, 1947, from the State of Pennsylvania into the State of Tennessee.

LABEL, IN PART: "Protecto contains Milk Whey Powder, Malt Sugar 200,000,000 of Acidurid Bacteria per 1. C. C. 16 ozs. * * * Expir. date Apr. 2, 1947."

NATURE OF CHARGE: Misbranding, Section 502 (a), the label statements "Contains * * * 200,000,000 of Acidurid Bacteria per 1. C. C. * * * Expir. date Apr. 2, 1947" were false and misleading, since the statements represented and suggested that prior to April 2, 1947, the article would contain not less than 200,000,000 acidurid bacteria per 1 cc. The article on a date prior to April 2, 1947, namely, March 17, 1947, contained less than .4 percent of the acidurid bacteria represented.

The article was alleged also to be misbranded under the provisions of the law applicable to foods, as reported in notices of judgment on foods.

DISPOSITION: A plea of not guilty having been entered, the case came on for trial before the court without a jury on the basis of the stipulation and briefs of the parties. On July 1, 1948, the court found the defendant not guilty and handed down the following opinion:

WELSH, JR., *District Judge:* "This is a prosecution begun by information, containing two counts, charging Bess J. Levine, an individual trading as Miracle Food Company, with violation of the Act of Congress of June 25, 1938, c. 675, 52 Stat. 1040, 21 U. S. C. Section 301–392, known as the Federal Food, Drug, and Cosmetic Act.

"The defendant, Bess J. Levine, is registered under the Fictitious Names Act of Pennsylvania as owner of the Miracle Food Company and has her principal place of business at 218 North 62nd Street, Philadelphia, Pennsylvania. The Miracle Food Company is the successor to Miracle Health Food Company, formerly operated at 259 South 11th Street, Philadelphia, Pennsylvania, by the defendant.

"In 1936, the defendant, Bess J. Levine, commenced to operate the business of exploiting a line of 'health foods.' Among the health foods and dietary remedies promoted by the defendant was the product 'Protecto' represented as a culture containing large numbers of Lactic acid bacilli.

"The product is manufactured by the Earp Laboratories, Caldwell (Bloomfield), New Jersey. It is shipped to the defendant unlabeled. It is then labeled by the defendant on the basis of the analysis supplied by the Earp Laboratories. Finally, the product is shipped by the defendant repacked and under her own label in interstate commerce.

"The trial was without a jury and the following is the stipulation entered into by counsel for the government and for the defendant:

STIPULATION

It is hereby stipulated and agreed by and between counsel for the government and counsel for the defendant, Bess J. Levine, an individual trading as Miracle Food Company, that the following facts may be considered by this Court as true and correct for the purpose of the case, and are offered by the respective parties in lieu of evidence thereof; That on or about January 29, 1947 the Miracle Food Company, 259 South 11th Street, Philadelphia 7, Pennsylvania, shipped via Super Service Motor Truck from 259 South 11th Street, Philadelphia 7, Pennsylvania, to Health Food Store, 206 North Cleveland Curb Market, Memphis, Tennessee, certain articles of foods and drugs including 12 bottles each containing 16 ounces, the said bottles bearing labels as follows: and hereinafter referred to as "Protecto"—

"Protecto"
contains
Milk Whey Powder, Malt Sugar
200,000,000 of Acidurid Bacteria
per 1 C. C.
Lactose
16 ozs. $1.25
Made for
MIRACLE FOOD CO.
Philadelphia, Pa.
Expir. date (stamped) Apr. 2, 1947

Directions
Average dose 2 tablespoons of Protecto after each meal or according to your physicians instructions.
Can be added to Tomato Juice

ENEMAS
Protecto is a splendid culture for Enemas. After taking enema add 2 tablespoons of Protecto to 4 oz. of fresh water and retain as long as possible. Shake well before using.
Keep Protecto in cool place

That on March 7, 1947 Hilding C. Olson, a duly authorized inspector of the Federal Security Agency, Food and Drug Administration, purchased from the said Health Food Store, 206 North Cleveland Curb Market, Memphis, Tennessee, two bottles, each containing 16 ounces of Protecto; That the said inspector designated the said bottles of Protecto as an official sample #41–022 H of the Food and Drug Administration. That at the time this sample was purchased Gladys Norris, owner of the Health Food Store, the consignee, identified the said article as being portion of a shipment received by the Health Food Store on or about January 31, 1947 via Cook Truck Lines, Inc., from the Miracle Food Company, 259 South 11th Street, Philadelphia 7, Pennsylvania, in response to an order previously given by the Health Food Store and covered by freight bill #22365, dated January 31, 1947 issued by Cook Truck Line, Inc. on which freight bill shows as connecting line reference "Super Serv. P. 36907," and an invoice dated January 30, 1947 issued by Miracle Health Food Company, Philadelphia 7, Pennsylvania, to Health Food Store, Memphis, Tennessee. That copies of these records were furnished the inspector by the consignee, Health Food Store, at the time of this sample purchase. That the Miracle Health Food Company, as shown on this invoice, is one and the same as Miracle Food Company located at 259 South 11th Street, Philadelphia 7, Pennsylvania:

That the said inspector paid the sum of $2.50 by United States Government voucher for the said articles which were immediately securely wrapped and sealed and identified by him upon the labels thereof with the legend "41–022 H 3–7–47 H. C. O." and upon the official seals the legend "41–022 3–7–47 Hilding C. Olson":

That this sample so collected, identified and sealed, was delivered to the laboratory of the Food and Drug Administration. That analysis established that the article labeled in part "Protecto contains * * * 200,000,000 of the Acidurid Bacteria per 1. C. C. contained viable acidophilus types of bacteria less than .4% of the 200,000,000 per C. C. declared on the label.

That the business address of the defendant, Bess J. Levine, trading as Miracle Food Company, through and during January 1947 was 259 South 11th Street, Philadelphia 7, Pennsylvania, and that her present business address is 218 North 62nd Street, Philadelphia, Pennsylvania; that the defendant, Bess J. Levine, was at the time of shipment here involved, and is now, the sole owner of Miracle Food Company.

"1. There can be no doubt under the facts stipulated above that there was a misbranding of the food or drug in question.

"2. A defendant in a prosecution under the Federal Food, Drug, and Cosmetic Act is not entitled to assert as a defense his or her lack of intent to violate the Act. United States vs. Dotterweich, 320 U. S. 277; United States vs. Greenbaum, 138 F. 2d 437. Justice Frankfurter speaking for the Court in United States vs. Dotterweich states:

The prosecution to which Dotterweich was subjected is based on a now familiar type of legislation whereby penalties serve as effective means of regulation. Such legislation dispenses with the conventional requirement for criminal conduct-awareness of some wrongdoing. In the interest of the larger good it puts the burden of acting at hazard upon a person otherwise innocent but standing in responsible relation to a public danger. United States vs. Balint, 258 U. S. 250. And so it is clear that shipments like those now in issue are punished by the statute if the article is misbranded or adulterated, and that the article may be misbranded or adulterated without any conscious fraud at all. It was natural enough to throw this risk on shippers with regard to the identity of their wares * * * United States vs. Johnson, 221 U. S. 488, 497–98.

"3. It is the contention of the defendant that she is exempt from prosecution by virtue of Section 303 (c) of the Act. Section 303 (a) provides that any person who violates any of the provisions of Section 301 shall be guilty of a misdemeanor and shall on conviction thereof be subject to a fine or imprisonment or both. Section 303 (c) provides inter alia:

No person shall be subject to the penalties of subsection (a) of this Section, (1) for having received in interstate commerce any article and delivered it or proffered delivery of it, if such delivery or proffer was made in good faith, unless he refuses to furnish on request of an Officer or employee duly designated by the Administrator the name and address of the person from whom he purchased or received such article and copies of all documents, if any there be, pertaining to the delivery of the article to him; or (2) for having violated Section 301 (a) or (d), if he establishes a guaranty or undertaking signed by, and containing the name and address of, the person residing in the United States from whom he received in good faith the article, to the effect, in case of an alleged violation of Section 301 (a), that such article is not adulterated or misbranded, within the meaning of this chapter, designating this chapter, or to the effect, in case of an alleged violation of Section 301 (d) that such article is not an article which may not, under the provisions of Section 404 or 505, be introduced into interstate commerce.

"4. This Court deems it unnecessary to determine whether or not the defendant falls within the scope of the exemption contained in subsection (2) relating to guaranty[1] for the reason that it is satisfied the facts and circumstances of

[1] It should be noted in passing, however, that letters of guaranty should receive a liberal, fair, and reasonable interpretation, so as to attain the object for which the instrument is designed and the purpose for which it is applied. Glaser, Kohn & Company vs. U. S. 224 Fed. 84.

the instant case disclose that the defendant has complied with the conditions set forth in subsection (1) and is therefore exempt from the penalties provided for in the Act. Our conclusion is substantiated by a consideration of the purpose of the exemption found in subsection (1). It is clear that it was designed to protect innocent dealers, such as the defendant, who receive goods shipped in interstate commerce. U. S. vs. Parfait Powder Puff Company, 136 F. 2d 1008. Thus, in Senate Report No. 493, 73d Congress, 2d Session, accompanying S. 2800, the Senate Committee reported as follows:

> The existing law provides for a guaranty whereby a dealer who buys on faith may be protected from liability under the law. This provision has safeguarded innocent dealers and has been extremely useful in fixing responsibility on guilty shippers. It would be continued in effect by paragraph (e). The bill affords in this paragraph further protection to the innocent dealer who distributes goods he has received from interstate sources. If he has failed to secure a guaranty he can escape penalties by furnishing the records in interstate shipment, thus allowing the prosecution to lie solely against the guilty shipper.

It is clear, we think, that the Act was intended to furnish protection to innocent receivers of goods shipped to them in interstate commerce in violation of the Act. The defendant in the instant case is such an innocent dealer and should be afforded the protection. Further, the defendant is exempt from liability under the Act for the record discloses she cooperated with the Department as required by subsection (1). In April, 1947, Mr. Bell, an Inspector of the Department, came to the defendant's place of business and took some of the Protecto away with him for examination and the defendant, at his request, informed him of the name and address of the Laboratory from which she purchased it and supplied him with all data in connection therewith which he requested.

"Accordingly, a verdict and judgment finding the defendant, Bess J. Levine, an individual, trading as Miracle Food Company, not guilty will be entered."

2420. Misbranding of Johnson's Rheumatic Tonic and Blood Purifier. U. S. v. Nathan G. Johnson (Johnson Drug & Chemical Co.). Plea of guilty. Fine of $50 and sentence of 6 months in prison; prison sentence suspended and defendant placed on probation for 3 years. (F. D. C. No. 24242. Sample No. 73534–H.)

INFORMATION FILED: April 2, 1948, Northern District of Alabama, against Nathan G. Johnson, trading as the Johnson Drug & Chemical Co., Birmingham, Ala.

ALLEGED SHIPMENT: On or about August 1, 1947, from the State of Alabama into the State of Ohio.

PRODUCT: Analyses disclosed that the product was a turbid brown liquid containing water, isopropyl alcohol, camphor, a resin, and a small amount of nitrite.

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements on the label of the article were false and misleading, since they represented and suggested that the article would be efficacious in the cure, mitigation, and treatment of rheumatism, paralysis, fits, catarrh of the head, asthma, blood poison, colds, cramps in the stomach, colic, dyspepsia, deafness, headache, palpitation of the heart, palsy or nervous trouble, piles, tumors, indigestion, female complaint, general poison, kidney troubles, spots under eyes, diarrhea, weak nerves, old sores, ulcers, stiff neck, liver complaint, and tonsillitis; that the article would be effective as a rheumatic tonic and blood purifier; and that it contained 50 percent of alcohol. The article contained less than 50 percent of alcohol, and it would not be efficacious for the purposes represented.

Further misbranding, Section 502 (b) (2), the bottles containing the articles bore no label containing a statement of the quantity of the contents in terms of weight or measure.

DISPOSITION: May 21, 1948. A plea of guilty having been entered, the court imposed a fine of $50 and sentenced the defendant to serve 6 months in prison. The prison sentence was suspended and the defendant was placed on probation for 3 years.

2421. Misbranding of Sa-Nos. U. S. v. Emil Wolfram (Wolfram Co.). Plea of guilty. Defendant fined $300, given sentence of 6 months in jail, which was suspended, and placed on probation for 6 months. (F. D. C. No. 24259. Sample Nos. 24408–K, 25015–K.)

INFORMATION FILED: June 4, 1948, Southern District of Ohio, against Emil Wolfram, trading as the Wolfram Co., Columbus, Ohio.

ALLEGED SHIPMENT: On or about April 7 and July 26, 1947, from the State of Ohio into the States of Iowa and Minnesota.

PRODUCT: Analyses disclosed that the product was a yellowish aqueous liquid containing boric acid, iodides, and aromatics.

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements on the label of the article were false and misleading, since the article would not be efficacious for the purposes represented The label statements represented that the article would be efficacious in the treatment of ulcers, catarrhal condition of the stomach, diseases of the mucous membrane, sore throat, tonsils, quinsy, sore nose, sore gums, tongue, and mouth, leucorrhea, piles, inflammation of the bladder, fissure of the anus, prolapsus of the lower bowel, eczema, tetter, eruption, old itching sores, burns, boils, carbuncles, wounds, itching diseases and similar conditions indicated by the abbreviation "etc.," severe burns, and scalds.

DISPOSITION: June 7, 1948. A plea of guilty having been entered, the defendant was fined $300 on count 1, sentenced to 6 months in jail on count 2, which sentence was suspended, and placed on probation for 6 months.

2422. Misbranding of Estrusol tablets and Estrusol in oil. U. S. v. Carroll Dunham Smith Pharmacal Co., Carroll Dunham Smith, Sr., Carroll Dunham Smith, Jr., and Joseph W. Kouten. Pleas of guilty. Company fined $500; fine suspended and company placed on probation for 1 year. Imposition of sentence against individuals suspended and they were placed on probation for 1 day. (F. D. C. No. 17878. Sample Nos. 1038–H, 3121–H, 3122–H, 31426–H, 31444–H.)

INFORMATION FILED: December 13, 1946, District of New Jersey, against Carroll Dunham Smith Pharmacal Co., a corporation, Orange, N. J.; Carroll Dunham Smith, Sr., president and treasurer; Carroll Dunham Smith, Jr., secretary; and Joseph W. Kouten, director of laboratories.

ALLEGED SHIPMENT: Between May 2, 1944, and June 22, 1945, from the State of New Jersey into the States of North Carolina and California and the District of Columbia.

LABEL, IN PART: *Estrusol tablets.* (Bottle) "Estrogenic substances from pregnant mares' urine; principally estrone and estradiol."

Estrusol in oil. (Vials) "Estrogenic substance * * * From pregnant mares' urine. Contains principally estrone and estradiol"; (cartons) "Natural estrogenic substances (principally estrone and estradiol) from pregnant mares' urine."

NATURE OF CHARGE: Misbranding, Section 502 (a), the statements from the above-quoted labels were false and misleading. These statements represented and suggested that the estrogenic material present in the articles was estrogenic substance as it occurs in and is extracted from pregnant mares' urine, whereas the estrogenic material was not estrogenic substance as it occurs in and is extracted from pregnant mares' urine.

DISPOSITION: November 7, 1947. Pleas of guilty having been entered, the corporation was fined $500; the fine was suspended and the corporation was placed on probation for 1 year. Imposition of sentence against the individuals was suspended and they were placed on probation for 1 day.

2423. Misbranding of Sul-Ray Colloidal Sulphur Mineral Baths. U. S. v. Sante Chemical Co., Inc., and Isaac Salzman. Pleas of guilty. Fine of $500 against defendants jointly. (F. D. C. No. 20206. Sample Nos. 4062–H, 4091–H.)

INFORMATION FILED: October 23, 1947, Southern District of New York, against the Sante Chemical Co., Inc., New York, N. Y., and Isaac Salzman, secretary.

ALLEGED VIOLATION: On or about December 15, 1944, and January 6, 1945, the defendants shipped from the State of New York into the State of Pennsylvania various quantities of *Sul-Ray Colloidal Sulphur Mineral Baths.* The defendants were charged also with giving a false guaranty. The guaranty was given by the defendants on or about February 7, 1945, to the National Healthaids, Inc., New York, N. Y., and guaranteed that drug preparations manufactured by the defendants and sold to the National Healthaids, Inc., would comply fully with the provisions of all laws, State or Federal. On or about February 28, 1945, the defendants delivered a quantity of *Sul-Ray Colloidal Sulphur Mineral Baths* to the National Healthaids, Inc., and on April 4, 1945, the latter firm shipped the product from the State of New York into the State of Pennsylvania. The product so guaranteed and shipped was misbranded.

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements in a leaflet entitled "Sul-Ray Colloidal Sulphur Mineral Baths," which was enclosed

with the article, were false and misleading since the article would not be effective for the purposes represented. The statements represented and suggested that the article would be effective in bringing the world's great mineral baths into one's home; that if added to the bath, it would bring relaxation and relief from pain and itching to those afflicted with rheumatism, arthritis, neuritis, lumbago, and generalized skin conditions; that it would stimulate the circulation and would refresh and vitalize; that it would bathe away aches, pains, and fatigue; that it would aid in eliminating body odors; that it would if used frequently and for long periods, remedy stubborn cases of long standing; that it would insure deep, refreshing sleep if used before retiring; that it would show indication of improvement in most users after the first few baths; that sulfur is a remedy for diseases generally; and that colloidal sulfur would penetrate the skin.

DISPOSITION: December 19, 1947. Pleas of guilty having been entered, the court imposed a fine of $500 against the defendants jointly.

2424. Misbranding of Firmo. U. S. v. Maynard H. Smith (Continental Sales Co.). Plea of guilty. Imposition of sentence suspended and defendant placed on probation for 1 year (F. D. C. No. 24243. Sample No. 90361–H.)

INFORMATION FILED: April 12, 1948, District of Columbia, against Maynard H. Smith, trading as the Continental Sales Co., in Washington, D. C.

ALLEGED SHIPMENT: The product and a booklet relating to the product and headed "The Anglo Arabic Importing Co., Ltd." were shipped on or about July 18 and July 7, 1947, respectively, from the District of Columbia into the State of Virginia.

PRODUCT: Analysis disclosed that the product contained approximately 3,375 International Units of estrogenic hormones per ounce.

LABEL, IN PART: "Firmo Contains 7500 I. U. of Natural Estrogenic Hormones Per Oz. of Cream."

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements in the labeling of the article were false and misleading since they represented and suggested that the article was an aphrodisiac; that it would be efficacious to maintain sexual potency to an extreme old age; and that it would be efficacious to increase the size of the male sex organ and to increase sexual vigor. The article was not an aphrodisiac, and it would not be efficacious for the purposes represented.

DISPOSITION: May 5, 1948. A plea of guilty having been entered, the court suspended the imposition of sentence and placed the defendant on probation for 1 year.

2425. Misbranding of Marvel Massage Cream and Marvel Bath. U. S. v. 37 Jars, etc. (F. D. C. No. 24453. Sample Nos. 16834–K to 16836–K, incl.)

LIBEL FILED: March 1, 1948, Eastern District of Wisconsin.

ALLEGED SHIPMENT: On or about November 15 and December 22, 1947, by the U. S. Products Co. (N. C. Douglas), from Wilmette, Ill.

PRODUCT: 37 1-pound jars of cream with loose labels reading in part "Marvel Massage Cream 1 Lb Net" and 50 red bags and 56 brown bags of powder with loose labels reading in part "Marvel Bath 6 Lbs. Net." Examination showed that the cream consisted essentially of water, epsom salt, and sodium sulfate, with small proportions of stearates and methyl salicylate; that the powder in the red bags consisted essentially of epsom salt, sulfur, powdered skim milk, and a perfume; and that the powder in the brown bags consisted essentially of epsom salt, sulfur, sodium carbonate, borax, common salt, and a perfume.

NATURE OF CHARGE: Misbranding, Section 502 (a), the label statement "A Reducing Aid for normal overweights" was false and misleading, since the article was not effective in promoting loss of weight.

DISPOSITION: April 20, 1948. Default decree of condemnation and destruction.

2426. Misbranding of La Toja Bath, La Toja Toilet Soap, and La Toja Mud Soap. U. S. v. 97 Jars, etc. (F. D. C. No. 23182. Sample Nos. 6542–H to 6544–H, incl.)

LIBEL FILED: June 12, 1947, Middle District of Pennsylvania.

ALLEGED SHIPMENT: On or about December 12, 1946, and March 11, 1947, by La Toja Products, Inc., from New York, N. Y.

PRODUCT: 97 14-ounce jars of *La Toja Bath*, 147 cartons of *La Toja Toilet Soap*, and 97 cartons of *La Toja Mud Soap* at Scranton, Pa., together with a number

of leaflets entitled "La Toja Soap from the Salts of the Famous Mineral Waters of La Toja" and a number of booklets entitled "La Toja Toilet Preparations" and "La Toja Salts Their Incorporation in La Toja Baths." Examination showed that the *La Toja Bath* consisted essentially of salt and water, with small proportions of other inorganic compounds; and that the *La Toja Toilet Soap* and the *La Toja Mud Soap* consisted essentially of soap, water, and salt, with small proportions of other inorganic compounds.

LABEL, IN PART: "La Toja Bath," "La Toja The Natural Mineral Salts Soap Toilet Soap [or "Mud Soap"]."

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements in the labeling of the articles were false and misleading, since the articles would not be effective for the purposes claimed. The false and misleading statements regarding the articles were to the following effect:

That the *La Toja Bath* was effective in the treatment of arthritis, arthritis deformans, rheumatism, neuritis, sciatica, lumbago, gout, skin disease, and nervous conditions; and that it would exert a sedative effect and promote profound and refreshing slumber;

That the *La Toja Toilet Soap* was effective in the treatment of eczema, psoriasis, acne, itch, muddy complexion, dandruff, and baldness due to dandruff; that it would restore the porosity of the skin and promote cutaneous respiration and elimination; that it would maintain or restore good health; that it would promote powerful actions, both local and general; and that it would penetrate to the deepest layers of the epidermis and exert a stimulating effect;

That the *La Toja Mud Soap* was effective in the treatment of arthritis, rheumatism, eczema, psoriasis, acne, itch, muddy complexion, dandruff, and baldness due to dandruff; that it would restore the porosity of the skin and promote cutaneous respiration and elimination; that it would maintain or restore good health; that it would promote powerful action, both local and general; and that it would penetrate to the deepest layers of the epidermis and exert a stimulating effect.

DISPOSITION: February 10, 1948. Default decree of condemnation and destruction.

2427. Misbranding of Dapper Hair and Scalp Tonic. U. S. v. 21 Bottles, etc. (F. D. C. Nos. 24388, 24389. Sample Nos. 19134–K, 19135–K.)

LIBEL FILED: March 19, 1948, Eastern District of Kentucky.

ALLEGED SHIPMENT: On or about February 17, 1948, by the King Drug Co., from Cincinnati, Ohio.

PRODUCT: 37 1-pint bottles and 42 8-ounce bottles of *Dapper Hair and Scalp Tonic* at Covington and Newport, Ky., together with one poster entitled "Why be bald," which was shipped with the product. Examination showed that the product was a perfumed liquid consisting essentially of water, alcohol, pilocarpine hydrochloride, and vitamin B.

LABEL, IN PART: (Bottle) "Dapper Hair and Scalp Tonic Contains Vitamin B"; (poster) "Why be bald? * * * Vitamin B Puts Hair on Jap Heads Bare * * * Two Nagoya University professors claimed today they have cured baldness by injecting Vitamin B into the scalp."

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements in the labeling of the article were false and misleading, since they represented and suggested that the article was effective in promoting the growth of hair and that vitamin B contributes in some manner to the value of a hair preparation. The article was not effective in promoting the growth of hair, and vitamin B does not contribute to the value of a hair preparation.

DISPOSITION: April 12, 1948. Default decree of condemnation and destruction.

2428. Misbranding of Gingisol. U. S. v. 69 Bottles * * *. (F. D. C. No. 23909. Sample No. 18143–K.)

LIBEL FILED: November 14, 1947, Eastern District of Tennessee.

ALLEGED SHIPMENT: On or about October 14, 1947, by Gingisol Laboratories, from Cleveland, Ohio.

PRODUCT: 69 8-ounce bottles of *Gingisol* at Chattanooga, Tenn. Examination showed that the product contained potassium phenolate and not more than an inconsequential amount, if any, of fluorides.

LABEL, IN PART: "Dr. Barben's Gingisol."

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements on the label were false and misleading. These statements represented and suggested that the article would be efficacious in the treatment and prevention of gingivitis and pyorrhea; that it would be efficacious to restore soft, spongy, bleeding gums to a healthy pink color, and to help keep gums firm and healthy; that it would cause swelling, bleeding, and tenderness in gums to subside; that it would aid materially in the healing process after tooth extractions; that it would be efficacious in the treatment of abscessed teeth and infected gums and tonsils; that it would aid in the correction of the chief causes of rheumatism, heart trouble, kidney disorders, stomach trouble, and nervous disorders; and that it would prevent the absorption of germs and poisons developing in diseased teeth and infected gums and tonsils. The article would not be effective in the prevention or treatment of the diseases, symptoms, and conditions stated and implied.

DISPOSITION: April 9, 1948. Default decree of condemnation and destruction.

2429. Adulteration and misbranding of vitamin B-complex tablets. U. S. v. 258 Dozen Cartons, etc. (F. D. C. No. 19939. Sample No. 20898–H.)

LIBEL FILED: On or about June 21, 1946, Western District of Missouri.

ALLEGED SHIPMENT: On or about September 1, 1943, by Major Vitamins, Inc., from New York, N. Y.

PRODUCT: 258 dozen cartons, each carton containing 100 tablets, and 30 dozen cartons, each carton containing 200 tablets, of *vitamin B-complex tablets* at Kansas City, Mo. Examination showed that the product contained less than the declared amount of vitamin B_1.

LABEL, IN PART: "Major-B Brand Natural B-Complex Vitamins with added thiamine."

NATURE OF CHARGE: Misbranding, Section 502 (a). The article was alleged also to be adulterated and misbranded under the provisions of the law applicable to foods, as reported in notices of judgment on foods, No. 13196, in which is set forth the nature of the charge under Section 502 (a).

DISPOSITION: October 30, 1946. The product was adjudged misbranded and was ordered delivered to a charitable institution.

2430. Misbranding of Nature's Minerals. U. S. v. 7 Cases and 400 Cards * * *. (F. D. C. No. 23673. Sample No. 73532–H.)

LIBEL FILED: September 5, 1947, Northern District of Ohio.

ALLEGED SHIPMENT: On or about June 6, 1947, by the Nature's Mineral Food Co., from Indianapolis, Ind.

PRODUCT: 7 cases, each containing 12 bottles, of *M. F. Co's Nature's Minerals* and 400 cards accompanying the product entitled "Now a Mineral Health Resort in Your Home!" at New Philadelphia, Ohio. Examination of a sample of the product showed that it contained the substances listed on the label.

LABEL, IN PART: "M. F. Co's Nature's Minerals 270 Tablets A Composition of Minerals Comprising Calcium Phosphate, Iodized Salt, Calcium Carbonate, Magnesium Sulphate (Epsom Salts), Sodium Phosphate, Sulphur Sublimed, Iron Sulphate and Potassium Iodide."

NATURE OF CHARGE: Misbranding, Section 502 (a), the statements on the cards which accompanied the product were false and misleading. These statements represented and suggested that the product was effective in removing waste matter that causes acidosis, anemia, constipation, headache, lumbago, neuritis, rheumatism, sciatica, kidney and bladder trouble, nervousness, gastric ulcers, and digestive troubles; that it was effective for indigestion, rheumatism, soreness of the muscles, choking goiter, kidney trouble, backache, stomach ulcers, gout, diseases which attack the body, skin eruptions, and pain; that it was effective to work up gastric juice, make food digest, loosen joints, restore health, build up shrunken and decayed tissues, give one ambition, make eyes sparkle, prevent premature aging, restore pep and spring to the gait, and supply health and pleasure; and that it would be effective to obviate the necessity for goiter operations. The article would not be effective for the purposes so represented.

In addition certain statements on the accompanying cards were false and misleading, since they represented that the use of the article would be equivalent to a sojourn at a resort in its effect on one's health, and that its use would

result in vigorous health of the user, whereas the article would not have such effect.

DISPOSITION: March 15, 1948. Default decree of condemnation and destruction.

2431. Misbranding of millet cereal. U. S. v. 38 Cases, etc. (and 1 other seizure action). (F. D. C. Nos. 24118, 24172. Sample Nos. 9271–K, 15106–K, 15107–K.)

LIBELS FILED: December 9 and 12, 1947, Northern District of Illinois and Eastern District of New York.

ALLEGED SHIPMENT: On or about October 7, 9, 15, and 30, 1947, by the Red Mill Products Co., from St. Paul, Minn.

PRODUCT: 38 cases and 50 cases of *millet cereal* at Chicago, Ill., and Brooklyn, N. Y., respectively, together with a number of accompanying leaflets entitled "Red Mill Proso Millet Cereal." Each case contained 12 1-pound packages. Examination showed that the product was ground millet.

LABEL, IN PART: "Red Mill Proso Millet Cereal."

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements in the leaflets were false and misleading since they represented and suggested that the article would furnish substantial quantities of all essential food elements; and that it would be effective to improve health, to build firm, healthy flesh, to insure vigor and energy, to prevent all chronic diseases, to prevent cancer, tuberculosis, and soft teeth, to provide minerals important to the body not provided by a good varied diet, and to build tall, sturdy bodies. The article would not furnish substantial quantities of all essential food elements, and it would not be effective for the purposes represented.

The article was alleged also to be misbranded under the provisions of the law applicable to foods, as reported in notices of judgment on foods.

DISPOSITION: January 29 and March 8, 1948. Default decrees of condemnation and destruction.

2432. Misbranding of Pyo-Gon. U. S. v. 57 Bottles, etc. (F. D. C. No. 24382. Sample No. 28035–K.)

LIBEL FILED: March 30, 1948, District of Colorado.

ALLEGED SHIPMENT: From Los Angeles, Calif., by Pyo-Gon Laboratories, Inc. The product was shipped on or about February 16, 1948, and a number of folders and leaflets were shipped on or about December 18, 1947.

PRODUCT: 57 1-pint bottles of *Pyo-Gon* at Denver, Colo., together with a number of folders entitled "Doctor, are you up a Stump?" and leaflets outlining reports from various commercial laboratories and colleges.

LABEL, IN PART: "Pyo-Gon * * * Contains the following per 1000 cc: Chondrus . . . 7 gms Phenol Iodine Iodophenols . . . 20 cc Boric Acid . . . 7 gms Oil of Eucalyptol Oil of Peppermint Methyl Salicylate . . . 0.06 cc Tincture Metaphen . . . 0.2 cc."

NATURE OF CHARGE: Misbranding, Section 502 (a), the statements "Pyo-Gon" and "Antiseptic Analgesic" on the label, and representations in the folders and leaflets were false and misleading. These statements represented and suggested that the article would cause pus to go; that it possessed germicidal and significant antiseptic properties; that it was an effective treatment for nonresponding inflammation, irritation, or infection, dermatitis, X-ray lesions, fissure, fistula, colitis, amoeba infections, congestion and infection in malignancy areas, conjunctivitis, iritis, corneal ulcers and injuries, chemical burns, otitis media and external, sinusitis, tonsillitis, laryngitis (acute), gonorrhea, leucorrhea, trichomonas, endometritis, cervicitis, cystitis, prostate inflammation, erysipelas, gangrene—toxic, diabetic or arterial obliterans, carbuncles, furunculosis, abscesses, ulcerations, and bed sores; that it would aid in protecting adjacent tissues against mixed infections in malignancy and would aid in venereal prophylaxis; that it would prevent stitch abscesses; that it would aid in the prevention of influenza, intestinal type of influenza, intestinal and focal toxemia, arthritis (toxic) gastric ulcer, duodenal ulcer, thyroid deficiency, and cystic goiter; that it was effective as a germicide both internally and externally; that it possessed surface analgesic and healing properties; that it would promote rapid healing; and that its use would render unnecessary sterilization of dressings. The article did not possess germicidal or significant antiseptic properties; its use would not render unnecessary sterilization of dressings; and it would not be effective for the purposes represented.

DISPOSITION: May 25, 1948. Default decree of condemnation and destruction.

2433. Misbranding of Rosex Vaginal Protective. U. S. v. 23 Cartons * * *. (F. D. C. No. 24484. Sample No. 27249–K.)

LIBEL FILED: March 18, 1948, Western District of Tennessee.

ALLEGED SHIPMENT: On on about October 17, 1947, by Rosex Laboratories, from St. Louis, Mo.

PRODUCT: 23 cartons each containing a nozzle and one tube of *Rosex Vaginal Protective* at Memphis, Tenn. The label stated that the product was composed of glycerin, oxyquinoline, and boric acid in a suitable base.

LABEL, IN PART: "Rosex A Superior Vaginal Protective Net Weight 2 Oz."

NATURE OF CHARGE: Misbranding, Section 502 (a), the label statement "A Superior Vaginal Protective" was false and misleading, since the article would not protect against the various disease conditions of the vagina.

DISPOSITION: April 21, 1948. Default decree of condemnation and destruction.

2434. Misbranding of adhesive bandages. U. S. v. 238 Cartons * * *. (F. D. C. No. 24308. Sample No. 10276–K.)

LIBEL FILED: January 29, 1948, Eastern District of New York.

ALLEGED SHIPMENT: On or about October 20 and 29, 1947, by Johnson & Johnson, from New Brunswick, N. J.

PRODUCT: 238 cartons, each containing 12 retail packages, of *adhesive bandages* at Brooklyn, N. Y. Each retail package contained 36 assorted *adhesive bandages.*

LABEL, IN PART: (Packages) "Tyro-thri-cin Pad Antiseptic Band-Aid Sterile Adhesive Bandage."

NATURE OF CHARGE: Misbranding, Section 502 (a), the statements in the labeling, "Antiseptic," "Tyro-thri-cin * * * an organic antiseptic which is derived by natural processes," and "Kills—Instead of Merely Checking Germ Growth," were false and misleading as applied to the article, which was neither antiseptic nor germicidal.

DISPOSITION: March 22, 1948. Johnson & Johnson, claimant, having admitted the allegations of the libel, judgment of condemnation was entered and the product was ordered released under bond for relabeling under the supervision of the Food and Drug Administration.

2435. Misbranding of Dr. Johnson's Private Formulas Nos. 1, 4, and 5, laxative tablets, and rectal pipes. U. S. v. Dr. O. A. Johnson Rectal Clinic. Plea of nolo contendere. Fine, $100 and costs. (F. D. C. No. 24237. Sample No. 99701–H.)

INFORMATION FILED: On or about March 5, 1948, Western District of Missouri, against the Dr. O. A. Johnson Rectal Clinic, a corporation, Kansas City, Mo.

ALLEGED SHIPMENT: On or about July 30, 1947, from the State of Missouri into the State of Oklahoma.

PRODUCT: A combination treatment consisting of 2 tubes of *Formula No. 1*, 1 tube of *Formula No. 4*, 1 tube of *Formula No. 5*, 1 box of *laxative tablets*, and *3 rectal pipes.*

LABEL, IN PART: "Dr. Johnson's Private Formula No. 1. Analgesic—Anti-Pruitic Active Ingredients—Menthol Synthetic, Camphor, Oil Eucalyptus, Carbolic Acid"; "Dr. O. A. Johnson's Private Formula No. 4 Astringent—Local Hemostatic Active Ingredients—Tannic Acid in Methylene Blue and Petrolatum Base"; "Dr. O. A. Johnson's Private Formula No. 5 Astringent—Emollient Active Ingredients: 6½% Alcohol by Volume. Calendula Off (Marigold), Mangifera Ind (Mango Gum), Hamemelis, (Witch Hazel), Ichthymall"; and "Laxative Tablets. Each Tablet Contains: Extract Belladonna . . . ⅛ grain (1/640 grain total Alkaloids) Ext. Cascara Sagrada, Oleoresin Ginger, Aloin, Podophyllin."

NATURE OF CHARGE: Misbranding, Section 502 (a), the labeling of the article, which included a circular entitled "Good News," leaflets entitled "The Best Proof of All" and "Directions for using," and a number of letters addressed to the consignee of the article, contained statements which were false and misleading. These statements represented and suggested that the article when used in accordance with the directions in the labeling would be an adequate treatment for piles; that it would be efficacious in the cure, mitigation, and treatment of rectal pain, soreness and bleeding of the rectum, bleeding and protruding piles, "Blind Piles," ulcerated rectum, and other rectal troubles;

and that it would be efficacious in the prevention of serious conditions resulting from piles. The article when used in accordance with the directions in the labeling would not be an adequate treatment for piles, and it would not be efficacious for the purposes represented.

DISPOSITION: March 5, 1948. A plea of nolo contendere having been entered, the court imposed a fine of $100 and costs.

2436. Misbranding of Two Way Stretched Plastic Film. U. S. v. Reed Laboratories, Inc., and Exa Glenn Reed. Pleas of nolo contendere. Fine of $250 and costs. (F. D. C. No. 23248. Sample No. 70819-H.)

INFORMATION FILED: November 12, 1947, Northern District of Ohio, against Reed Laboratories, Inc., Akron, Ohio, and Exa Glenn Reed, president.

ALLEGED SHIPMENT: On or about December 9, 1946, from the State of Ohio into the State of California.

PRODUCT: Examination showed that the product consisted of a thin transparent plastic-like film rolled on a cardboard cylinder.

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements in a circular entitled "A Preliminary Report on Q Energy," which was enclosed with the article, were false and misleading since they represented and suggested that the article would be efficacious to heal simple injuries four or five times faster than normal, to heal sores which had not responded to any other form of treatment, and to heal varicose ulcers, abdominal incisions, serious burns and sunburns, amputations, corns, and callouses; that it would be efficacious to reduce swellings and growths and varicose veins, to make wens and fatty tumors disappear, and to reduce and eliminate swellings from dropsical conditions, bruises, and similar conditions; that it would be efficacious to relieve asthma, pneumonia, and lung congestion, to treat stomach ulcers, colitis, gas, and other symptoms of indigestion, to correct constipation and diarrhea, and to relieve menstrual pains; that it would be efficacious to enable the user to sleep restfully, to fall asleep while still in pain, and to sleep through disturbances; that it would be efficacious to aid circulation and to relieve the pain of toothache, headache, arthritis, muscular aches, and other pain; that it would be efficacious to dissolve mineral deposits in the body such as occur in arthritis; and that it would be efficacious in the treatment of cancer and tuberculosis. The article would not be efficacious for the purposes represented and suggested.

DISPOSITION: December 9, 1947. Pleas of nolo contendere having been entered, the court imposed a single fine of $250, together with costs.

2437. Misbranding of Cosmo-Light device. U. S. v. Fred Gerkey. Plea of guilty. Fine, $500. (F. D. C. No. 24224. Sample No. 70813-H.)

INFORMATION FILED: March 31, 1948, Western District of Missouri, against Fred Gerkey, Mission, Kans.

ALLEGED SHIPMENT: On or about November 15, 1946, from the State of Missouri into the State of California.

PRODUCT: Examination disclosed that the device consisted essentially of a high-voltage transformer of the type used in neon signs, together with the wiring, and a series of tubes constructed like neon tubes. The tubes were connected with the terminals of the transformer in such manner that no current passed through the tubes directly, but so that a small amount of current flowed between closely adjacent tubes, causing a slight illumination. The close proximity of the tubes caused a corona discharge to take place between them. This discharge was responsible for the fizzing noise when the device was in operation and for the production of ozone.

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements in the labeling of the device, including a circular entitled "Facts-Color-Ozone" which was shipped prior to the device, and a leaflet entitled "Instructions" which was shipped with the device, were false and misleading since the device would not be efficacious for the purposes represented. The statements represented and suggested that the device would be efficacious in healing and preventing disease and in the treatment of polio, sprained wrist, bladder trouble, prostate ailments, colitis, lung trouble, pain in leg, blindness, arthritis, paralysis, asthma, every kind of condition, and sinus trouble.

DISPOSITION: May 14, 1948. A plea of guilty having been entered, the court imposed a fine of $500.

2438. Misbranding of Nascent Haloid Vapor Generator device. U. S. v. 1 * * *. (F. D. C. No. 24395. Sample No. 31707–K.)

LIBEL FILED: December 30, 1947, Southern District of California.

ALLEGED SHIPMENT: Between the approximate dates of March 28 and April 26, 1947, by Rittenhouse & Revere, Inc., from Albuquerque, N. Mex.

PRODUCT: 1 device known as *Nascent Haloid Vapor Generator* at Los Angeles, Calif. Examination showed that the device was designed to produce gas by electrolysis of a salt solution. Analysis showed that the gas produced contained chlorine and did not contain hydrogen chloride.

LABEL, IN PART: "Nascent Haloid Vapor Germicidal Respiratory Therapy."

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements in an instruction manual shipped with the device were false and misleading since they represented and suggested that the gas produced by the device was not chlorine, but was hydrogen chloride; and that the inhalation of gas produced by the device was effective for germicidal respiratory therapy and in the treatment of sinus infections, acute and chronic rhinitis, common colds, asthma, bronchitis, hay fever, internal infections, unlocated foci of infection, arthritis, and rheumatism. The gas produced by the device contained chlorine, and inhalation of gases from the device was not effective for the conditions represented.

DISPOSITION: May 19, 1948. Rittenhouse & Revere, Inc., claimant, having consented to the entry of a decree, judgment of condemnation was entered and the device was ordered released under bond for relabeling under the supervision of the Federal Security Agency.

2439. Misbranding of Vacuum Stimulator device. U. S. v. 2 * * *, etc. (F. D. C. No. 24140. Sample No. 30051–K.)

LIBEL FILED: December 1, 1947, District of Arizona.

ALLEGED SHIPMENT: On or about October 14, 1947, by the Ricard Mfg. Co., from Omaha, Nebr.

PRODUCT: 2 cartons each containing 1 device known as a *Vacuum Stimulator*, or "Prostate Gland Stimulator," at Phoenix, Ariz., together with two instruction sheets entitled "Instructions for Using our Vacuum Stimulator to the Male Organ" and two circulars entitled "If You are young and robust, 'full of Pep' Don't Read This!" Examination showed that the device consisted of a clear plastic cylinder, one end of which was equipped with a soft rubber ring and the other end closed by a hand-operated vacuum pump.

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements in the circulars and instruction sheets were false and misleading, since they represented and suggested that the device was effective to overcome impotence and was effective in the treatment of disorders of the male sexual organs, whereas the device was not effective for such purposes.

DISPOSITION: April 6, 1948. Default decree of condemnation and destruction.

2440. Misbranding of Therm-Aire heated bed pad. U. S. v. 15 Pads, etc. (F. D. C. No. 24218. Sample No. 12618–K.)

LIBEL FILED: December 31, 1947, Eastern District of Pennsylvania.

ALLEGED SHIPMENT: On or about October 23, 1947, by the Therm-Aire Equipment Co., from Nashville, Tenn.

PRODUCT: 15 twin-size and 24 full-size *Therm-Aire heated bed pads* at Philadelphia, Pa., together with certain circulars enclosed in the boxes containing the devices. Examination showed that the devices were electrically heated bed pads.

LABEL, IN PART: (Circular entitled "Sleep Your Way to Health and Beauty") "The New Therm-Aire Heated Bed Pad Brings Quick Relief From Nerve Tension so Essential in Keeping up to Par * * * Keep Your health up to par * * * concentrated where it is needed most * * * along * * * center of the nervous system * * * Therm-Aire insures * * * release of nerve tension"; (circular entitled "Sleep Your Way to Health with Therm-Aire") "provides heat * * * along * * * central nervous system * * * supplying the body with heat energy so essential for maintaining good health."

NATURE OF CHARGE: Misbranding, Section 502 (a), the above-quoted and similar statements in the labeling of the article were false and misleading. These statements represented and suggested that with the use of the device, heat would be concentrated along the center of the nervous system and that the

device would keep health up to par, relieve nerve tension, and overcome insomnia. The use of the device would not cause heat to be concentrated along the center of the nervous system, and the device would not accomplish the results claimed.

DISPOSITION: January 15, 1948. The Therm-Aire Equipment Co., claimant, having consented to the entry of a decree, judgment of condemnation was entered and the devices were ordered released under bond for relabeling under the supervision of the Federal Security Agency.

DRUGS FOR VETERINARY USE

2441. Misbranding of Giles Veterinary Medicine. U. S. v. Giles Remedy Co. and Sanford F. Giles. Pleas of nolo contendere. Fine of $200 and costs against defendants jointly (F. D. C. No. 20191. Sample Nos. 15346–H, 17686–H.)

INFORMATION FILED: April 3, 1947, Northern District of Illinois, against the Giles Remedy Co., a corporation, Chicago, Ill., and Sanford F. Giles, president.

ALLEGED SHIPMENT: On or about April 5 and 10, 1946, from the State of Illinois into the State of Michigan.

PRODUCT: Analyses disclosed that the product consisted essentially of a solution of ether and camphor in a fixed oil.

LABEL, IN PART: "The Great Giles Veterinary Medicine."

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements appearing in the circulars entitled "Ship with Safety," "Why," "How to Treat Sick Animals," and "First Aid for Sick Animals," which were shipped to the Kalamazoo consignee prior to the shipment of the drug, and in the circular entitled "First Aid for Sick Animals," which was shipped to the Detroit consignee along with the drug, were false and misleading since the article would not be effective for the purposes, and would not fulfill the promises, of benefit stated and implied. The statements represented and suggested that the article would be effective in safeguarding horses from disease conditions and ailments; that it would be effective against "lay-ups," loss of stamina, and appetite; that it would be effective in building up resistance against any ailment; that it would be effective in preventing and relieving shipping fever, acclimating troubles, and ailments caused by exposure, chills, colds, fever, laryngitis, and influenza; that it would be effective in maintaining the health of cattle, horses, sheep, and other domestic animals, and would eliminate germ poison and remove congestion from any part of the body of animals; that it would be effective against udder troubles and vaginal affections; that it would improve the circulation and build up and tone the entire system of animals; that it possessed healing properties; that it would be a benefit and an aid in the natural delivery of healthy offspring; that it would be effective in the treatment of Bang's disease of cattle; that it would be effective in the treatment of sick animals and in the prevention and treatment of contagious abortion; that it would be effective to cure most any kind of sickness; that it would keep animals healthy and check slight sickness before it became worse; that it would be effective as an early treatment in cases where animals contracted some serious ailments; that it would be effective as health insurance for animals; that it would take the place of the services of a veterinarian and would save horse and cattle owners millions of dollars; that it would be effective in the prevention and treatment of horse and cow ailments; that it would be effective in the treatment of horse ailments, such as acclimating troubles, azoturia, chill, cough and cold, colic, congestion, constipation, diarrhea, distemper, fever, foot affections, indigestion, influenza, impaction of stomach, laryngitis, pink eye, pneumonia, sleeping sickness, sunstroke, and wounds; that it would be effective in the treatment of cow ailments, such as abortion, garget, colic, constipation, diarrhea, indigestion, inflammation of the intestines, milk fever, navel ill, scour in calves, stomach troubles, stomatitis, suppression of milk, and udder troubles; that when used as directed it would be effective as a first aid for sick animals and in the treatment of sick animals; that it would be effective in removing congestion and the cause of any ailment; that it would be effective against toxins of germs; that it would be effective in increasing the blood action and in stimulating the heart and other organs, enabling them to perform naturally; that it was an excellent tonic; that it would subdue fever and allay inflammation; that it would be effective in the treatment of tired horses and in the general care of sick horses; that it would

be effective as a first aid measure of horses' ailments, such as chills, fever, influenza, ozaena, nasal gleet, dry catarrh of the head, distemper, catarrhal fever, pink eye, pharyngitis (sore throat), laryngitis, abdominal and enteric influenza, strangles, affections of the lungs and bronchial tubes, bronchitis, pneumonia, pleuro-pneumonia, asthma, heaves, weak heart, thumps, purpura blood poisoning, bacterial poisoning, spinal meningitis, tetanus, enteritis, impaction of the stomach, stomach staggers, grass staggers, diarrhea, superpurgation, diarrhea of foals, indigestion, constipation, azoturia, worms, inflammation of the bladder, deep wounds, burns, scalds, scratches, cracked heels, grease, grapes, and eczema; that it would be effective in the retention of urine and bloody urine; that it would be effective in the treatment of fistula of the withers, poll evil, enlarged joints, shoe boil, capped elbow, foot affection, thrush, wounds and bruises of the coronet, nail punctures, corns, fistula of the coronet, contracted heels, laminitis, founder, lymphangitis, sunstroke, heat shock, hidebound, and moon blindness; that it would be effective as a first aid measure for cow ailments; that it would be effective at the first sign of illness; that it would be effective for milk fever of cattle, garget (congestion of the udder), and inflammation of the udder; that it would be effective against suppression of milk and in the prevention and treatment of tuberculosis and germ ailments; that it would be effective for tuberculosis of the lungs and tuberculosis affecting the glands; that it would be effective in the treatment of retention of the placenta and afterbirth and as a prevention and treatment of abortion of cows; that it would be effective in the treatment of diarrhea of newborn calves; that it would be effective in the treatment of umbilical hernia, navel ill, stomatitis, foot and mouth disease, stomach troubles, disease condition of the lungs and respiratory organs, eye infections, wounds and sores, jaundice, congestion of the liver, inflammation of the liver, fluke disease, and inflammation of the spleen; that it would keep animals well; and that it would be effective as a first aid measure against sheep ailments, such as affections of the air passages, bloat, foot troubles, eye and ear troubles, and worms.

DISPOSITION: June 16, 1947. Pleas of nolo contendere having been entered, the court imposed a fine of $200 and costs against the defendants jointly.

2442. Misbranding of Early Bird Anthelmintic and Early Bird Improved. U. S v. Hector Huard (Huard Laboratories). Plea of nolo contendere. Fine, $200. (F. D. C. No. 23256. Sample Nos. 57171–H, 74014–H.)

INFORMATION FILED: November 25, 1947, District of Connecticut, against Hector Huard, trading as Huard Laboratories, Norwich, Conn.

ALLEGED SHIPMENT: On or about September 16, 1946, and February 15, 1947, from the State of Connecticut into the States of Rhode Island and Massachusetts.

PRODUCT: Analyses disclosed that the *Early Bird Anthelmintic* was a mixture of a yellowish oil, atop a thin green aqueous sludge, containing, among other ingredients, castor oil, thymol, arecoline, and senna; and that the *Early Bird Improved* was a greenish oil mixed with a small amount of a semiliquid insoluble in the oil, with indications of the presence of oleoresin, male fern, arecoline, thymol, santonin, podophyllin, senna, and castor oil.

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements on the labels of the products, in a circular entitled "Stepping Ahead in Worm Therapy," which was shipped with the products, and in a circular entitled "Suggestions for Worming Your Dog," which was enclosed with the *Early Bird Anthelmintic*, were false and misleading. These statements represented and suggested that the articles would be effective in the removal of all species of worms infesting dogs, whereas the articles would not be effective for such purposes.

DISPOSITION: January 26, 1948. A plea of nolo contendere having been entered, the court imposed a fine of $100 on each of the two counts of the information.

2443. Adulteration and misbranding of Enricho No. 1 and Enricho No. 2. U. S. v. Dawe's Manufacturing Co. Plea of guilty. Fine, $1,500. (F. D. C. No. 23223. Sample Nos. 19334–H, 51504–H.)

INFORMATION FILED: December 4, 1947, Southern District of Illinois, against the Dawe's Manufacturing Co., a corporation, Peoria, Ill.

ALLEGED SHIPMENT: On or about March 21 and 27, 1946, from the State of Illinois into the States of Iowa and Minnesota.

PRODUCT: Analyses disclosed that the *Enricho No. 1* contained, per gram, 70 U. S. P. units of vitamin D, 50 U. S. P. units of vitamin A, more than 100 micrograms of riboflavin, approximately 86 micrograms of vitamin B_1, approximately 70 micrograms of ascorbic acid, and 119 micrograms of niacin; and that the *Enricho No. 2* contained, per gram, 200 U. S. P. units of vitamin D, 53 micrograms of riboflavin, 50 micrograms of vitamin B_1, less than 25 U. S. P. units of vitamin A, and approximately 80 micrograms of ascorbic acid and 75 micrograms of niacin.

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements on the labels of the articles were false and misleading, since they represented and suggested that the articles would be of aid to poultry and livestock in preventing and recovering from setbacks and sickness due to shortage of vitamins; that the use of the articles would insure the health of animals; that the articles would be efficacious by reason of their vitamin content in the cure, mitigation, treatment, and prevention of infections in poultry and livestock; that the *Enricho No. 1* would be efficacious in the prevention in poultry of low disease resistance, rickets and paralysis, and in the prevention in four-legged animals of low disease resistance, rickets, diarrhea, anemia, night blindness, nutritional scours, and paralysis; and that the *Enricho No. 1* would be efficacious in the treatment of weak, run-down, and convalescent birds and animals, backward flocks, sickly animals, and females during pregnancy and nursing. The articles would not be efficacious for the purposes represented.

The articles were alleged also to be misbranded under the provisions of the law applicable to foods, as reported in notices of judgment on foods.

DISPOSITION: January 5, 1948. A plea of guilty having been entered, the court imposed a fine of $1,500.

2444. Misbranding of Lewis Spray for Poultry, Lewis Worm Killer, and Lewis Muroil. U. S. v. The Lincoln Hatchery. Plea of nolo contendere. Fine of $75 and costs. (F. D. C. No. 21485. Sample Nos. 19641–H, 56508–H, 56510–H.)

INFORMATION FILED: June 24, 1947, District of Nebraska, against the Lincoln Hatchery, a corporation, Lincoln, Nebr.

ALLEGED SHIPMENT: On or about November 5, 1945, and March 15, 1946, from the State of Nebraska into the States of Iowa and Kansas.

PRODUCT: Analyses disclosed that the *Lewis Spray for Poultry* consisted chiefly of water and small amounts of formaldehyde, phenol, and glycerin; that the *Lewis Worm Killer* consisted of a brown powder containing a large amount of plant material and small amounts of nicotine and phenothiazine; and that the *Lewis Muroil* consisted chiefly of water and hydrochloric acid and a small amount of cod liver oil.

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements on the labels of the articles were false and misleading. These statements represented and suggested that the articles would be efficacious for the following purposes, whereas they would not be efficacious for such purposes:

That the *Lewis Spray for Poultry* would be efficacious in the cure, mitigation, and treatment of respiratory diseases of poultry, the symptoms of which are gasping for breath and difficulty in breathing; that the *Lewis Worm Killer* would be effective in killing all species of worms infesting poultry; and that the *Lewis Muroil* would be efficacious in the cure, mitigation, treatment, and prevention in poultry of coccidiosis, listlessness, lack of appetite, and bowel trouble.

DISPOSITION: June 28, 1948. A plea of nolo contendere having been entered, the court imposed a fine of $75 and costs.

2445. Misbranding of MBX Liquid for Poultry, Kolex Liquid for Poultry, FTC Liquid for Poultry, CWD Liquid for Poultry, and Noxaton. U. S. v. 7 Bottles, etc. (F. D. C. No. 23879. Sample Nos. 24423–K to 24426–K, incl., 24428–K.)

LIBEL FILED: October 30, 1947, Northern District of Iowa.

ALLEGED SHIPMENT: On or about May 11 and December 5, 1946, and May 19 and June 12, 1947, by the Northern States Poultry Service Co., from Luverne, Minn.

PRODUCT: 7 ½-gallon bottles and 11 1-quart bottles of *MBX Liquid for Poultry;* 2 1-gallon bottles, 4 ½-gallon bottles, and 6 1-quart bottles of *Kolex Liquid for Poultry;* 4 ½-gallon bottles and 7 1-quart bottles of *FTC*

Liquid for Poultry; 7 1-quart bottles of *CWD Liquid for Poultry;* and 1 15-pound drum of *Noxaton*, at George, Iowa, together with a number of leaflets entitled "Get More Eggs!" post cards entitled "Double the Aid with this Powerful Combination," and booklets entitled "Guide to Poultry Service," which were delivered to the consignee of the products by a salesman of the shipper on or about June 12, 1947.

Analyses disclosed that the *MBX Liquid for Poultry* consisted essentially of water, with small amounts of potassium chlorate, potassium dichromate, and volatile oils such as camphor, eucalyptus, guaiacol, and creosote; that the *Kolex Liquid for Poultry* consisted essentially of water, with small proportions of potassium nitrate, potassium chlorate, potassium dichromate, and epsom salt; that the *FTC Liquid for Poultry* consisted essentially of water, with small amounts of zinc, sodium, calcium and copper phenolsulfonates; that the *CWD Liquid for Poultry* consisted essentially of water, with small proportions of calcium, sodium, zinc and copper phenolsulfonates with ipecac and extract of quebracho; and that the *Noxaton* consisted essentially of a powdered mixture containing copper and iron sulfates, and plant material including fragments of seeds, bark, roots, woody leaves, resins, starch, and small amounts of nicotine, potassium iodide, and strychnine.

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements in the labeling of the articles were false and misleading, since the articles when used as directed were not effective for the purposes represented. The statements represented and suggested that the *MBX Liquid for Poultry* when used as directed was effective in the treatment of fowl pox, dry pox, wet pox (diphtheritic type), bronchitis, laryngotracheitis, colds, roup, lesions of fowl pox, swellhead, sinusitis, and bowel troubles; that the *Kolex Liquid for Poultry* when used as directed was effective in the treatment of botulism, commonly known as limberneck in poultry; that the *FTC Liquid for Poultry* when used as directed was effective in the treatment of intestinal disturbances in chickens, turkeys, ducks, and geese; that the *CWD Liquid for Poultry* when used as directed was effective in the treatment of coccidiosis of chickens and turkeys, and of blackhead in turkeys; and that the *Noxaton* when used as directed was effective in the treatment and prevention of lazy hens, run-down conditions of flocks, fowl tuberculosis, fowl cholera, fowl typhoid, botulism (limberneck), fowl pox, dry pox, wet pox (diphtheritic type), laryngotracheitis, bronchitis, fowl paralysis (avian leukosis, complex leukosis, leukemia), coccidiosis, intestinal type coccidiosis, roup, colds, mycosis, blackhead in turkeys, lesions of fowl pox, swellhead, sinusitis, trichomoniasis, and hexamitiasis.

DISPOSITION: December 13, 1947. Default decree of condemnation and destruction.

2446. Misbranding of Semi-Solid Pig Emulsion. U. S. v. 17 Barrels * * *. (F. D. C. No. 15707. Sample No. 13528–H.)

LIBEL FILED: March 20, 1945, Southern District of Indiana.

ALLEGED SHIPMENT: On or about October 24, 1944, by the Consolidated Products Co., from Danville, Ill.

PRODUCT: 17 barrels, each containing 400 pounds, of *Semi-Solid Pig Emulsion* at Lebanon, Ind. Analysis showed that the product was a semisolid mixture of water, casein, lactose, mineral salts, and fats, including fish oil, and that it contained 9.27 percent of protein.

LABEL, IN PART: (Tag) "Guaranteed Analysis * * * Crude Protein, not less than 11.0%"; (folder headed "Complete Instructions for Feeding Semi-Solid Pig Emulsion") "Pigs and Sows Necro Treatment A half-pound of Semi-Solid Pig Emulsion per day per pig from weaning to market, is worth a hundred pounds per pig of cure. Feed it every day to safeguard your herd."

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements in the folder were false and misleading, since they represented and suggested that the product would be effective in the prevention and treatment of "necro" or necro-enteritis in pigs and sows. The product would not be effective for such purposes.

The product was alleged also to be misbranded under the provisions of the law applicable to foods, as reported in notices of judgment on foods, No. 13102.

DISPOSITION: The Consolidated Products Co., claimant, filed an answer admitting for the purpose of the instant case only, that the product was misbranded, but stating specifically that the admission was made without prejudice to the

right of the claimant to allege and prove in any other action that the product or any like or similar product was not a drug and was not misbranded. The claimant also consented to the entry of a decree of condemnation against the product. In accordance with the answer and consent of the claimant, judgment of condemnation was entered on September 7, 1945, and the product was ordered released under bond for the purpose of relabeling under the supervision of the Federal Security Agency. On October 29, 1945, the claimant filed a report with reference to the disposition of the product, alleging that by reason of a mistake made in good faith the product had been redelivered to the claimant and reprocessed and used in the feeding of hogs on an experimental farm owned by the claimant, prior to the entry of the decree of condemnation. On the same date, the court having found that the above-described disposition of the product was occasioned by a good-faith mistake, an order was entered providing for the cancellation of the bond and the release of the claimant and its surety from further liability thereon.

2447. Misbranding of lye. U. S. v. 78 Cases * * *. (F. D. C. No. 24367. Sample No. 21302–K.)

LIBEL FILED: March 4, 1948, Eastern District of Oklahoma.

ALLEGED SHIPMENT: On or about December 28, 1947, by the Bray Chemical Co., from Chicago, Ill.

PRODUCT: 78 cases, each containing 48 cans, of *lye* at Muskogee, Okla. Analysis showed that the product consisted essentially of 95.6 percent of sodium hydroxide or lye and a small amount of sodium carbonate.

LABEL, IN PART: (Cans) "13 Ounces Net Weight Griffin's High Test Lye."

NATURE OF CHARGE: Misbranding, Section 502 (a), the label statement "For Hogs—Griffin's Lye Is An Aid in Preventing Hog Cholera and Eradicating Worms" was false and misleading, since the article was not effective as an aid in preventing hog cholera and was not effective in eradicating worms which infest hogs.

The article was alleged also to be misbranded under the Federal Caustic Poison Act, as reported in notices of judgment on caustic poisons under that Act.

DISPOSITION: June 14, 1948. The Griffin Grocery Co., Muskogee, Okla., claimant, having consented to the entry of a decree, judgment of condemnation was entered and the product was ordered released under bond for relabeling under the supervision of the Federal Security Agency.

DRUG ACTIONABLE BECAUSE OF OMISSION OF, OR UNSATISFACTORY, INGREDIENTS STATEMENTS*

2448. Misbranding of Estrinol. U. S. v. Bellevue Laboratories, Inc., and Chiam Dick. Pleas of guilty. Fine of $100 against defendants jointly. (F. D. C. No. 20109. Sample No. 4447–H.)

INFORMATION FILED: January 29, 1948, Southern District of New York, against Bellevue Laboratories, Inc., New York, N. Y., and Chiam Dick, president.

ALLEGED SHIPMENT: On or about March 16, 1945, from the State of New York into the State of Pennsylvania.

NATURE OF CHARGE: Misbranding, Section 502 (e) (2), the article was fabricated from two or more ingredients, and its label did not bear the common or usual name of the active ingredients.

DISPOSITION: July 14, 1948. Pleas of guilty having been entered, the court imposed a fine of $100 against the defendants jointly.

DRUGS ACTIONABLE BECAUSE OF FAILURE TO BEAR AN ACCURATE STATEMENT OF THE QUANTITY OF THE CONTENTS**

2449. Misbranding of sulfathiazole tablets. U. S. v. 430 Bottles * * *. (F. D. C. No. 24495. Sample No. 7810–K.)

LIBEL FILED: March 18, 1948, Western District of New York.

ALLEGED SHIPMENT: On or about December 23, 1947, by the Atlanta General Distribution Depot, from Atlanta, Ga.

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*See also Nos. 2403, 2408, 2409.
**See also Nos. 2403, 2420.

PRODUCT: 430 bottles of *sulfathiazole tablets* at Buffalo, N. Y. Examination showed that each bottle contained approximately 665 whole tablets and broken pieces of approximately 335 tablets.

LABEL, IN PART: "1000 Tablets Sulfathiazole."

NATURE OF CHARGE: Misbranding, Section 502 (b) (2), the article failed to bear a label containing an accurate statement of the quantity of contents.

DISPOSITION: May 24, 1948. The Ziegler Pharmacal Co., Buffalo, N. Y., having appeared as claimant, judgment was entered ordering that the product be released under bond for reprocessing under the supervision of the Federal Security Agency.

2450. Misbranding of absorbent cotton. U. S. v. 20 Cartons * * *. (F. D. C. No. 24392. Sample No. 10412-K.)

LIBEL FILED: March 17, 1948, Eastern District of New York.

ALLEGED SHIPMENT: On or about January 8, 1948, by New Aseptic Laboratories, Inc., from Columbia, S. C.

PRODUCT: 20 cartons, each containing 1 gross packages, of *absorbent cotton at* Brooklyn, N. Y.

LABEL, IN PART: (Package) "2 Ozs. Salco Absorbent Cotton."

NATURE OF CHARGE: Misbranding, Section 502 (b) (2), the article failed to bear a label containing an accurate statement of the quantity of contents. (The article was short-weight.)

DISPOSITION: June 16, 1948. Default decree of condemnation. The product was ordered delivered for the use of a Federal hospital.

INDEX TO NOTICES OF JUDGMENT D. D. N. J. NOS. 2401 TO 2450

PRODUCTS

[2] (2405) Seizure contested. Contains findings of fact and conclusions of law.
[3] (2417) Permanent injunction issued.
[4] (2408) Prosecution contested.

SHIPPERS, MANUFACTURERS, AND DISTRIBUTORS

[2] (2405) Seizure contested. Contains findings of fact and conclusions of law.
[3] (2417) Permanent injunction issued.
[4] (2408) Prosecution contested.
[5] (2419) Prosecution contested. Contains opinion of the court.

[2] (2405) Seizure contested. Contains findings of fact and conclusions of law.
[5] (2419) Prosecution contested. Contains opinion of the court.

ERRATUM

D. D. N. J. 2331, p. 60. Under NATURE OF CHARGE, paragraph 2, line 4, delete "chronic eczema, and other skin conditions;" and substitute "condition suggested and implied in the abbreviation, 'etc.';"

U. S. GOVERNMENT PRINTING OFFICE: 1949

FEDERAL SECURITY AGENCY

FOOD AND DRUG ADMINISTRATION

NOTICES OF JUDGMENT UNDER THE FEDERAL FOOD, DRUG, AND COSMETIC ACT

[Given pursuant to section 705 of the Food, Drug, and Cosmetic Act]

2451–2500

DRUGS AND DEVICES

The cases reported herewith were instituted in the United States district courts by the United States attorneys acting upon reports submitted by direction of the Federal Security Administrator.

J. Donald Kingsley, *Acting Administrator, Federal Security Agency.*

Washington, D. C., *December 24, 1948.*

CONTENTS*

DEVICE ACTIONABLE BECAUSE OF POTENTIAL DANGER WHEN USED ACCORDING TO DIRECTIONS

2451. Misbranding of Gomco ring pessary. U. S. v. 62 Devices, etc. (F. D. C. No. 24856. Sample No. 14123–K.)

Libel Filed: June 7, 1948, Northern District of Illinois.

Alleged Shipment: Between December 15, 1947, and April 1, 1948, from Buffalo, N. Y., by the Gomco Surgical Mfg. Corp.

Product: 62 *Gomco ring pessary devices* at Chicago, Ill., together with two circulars entitled "Technique For The Use Of The Gomco Intrauterine Silver Ring Pessary." Examination showed that the device was a metallic ring, approximately one inch in diameter, which was fashioned from a coiled spring.

Label, in Part: "Gomco Ring Pessary."

Nature of Charge: Misbranding, Section 502 (j), the device was dangerous to health when used with the frequency and duration recommended and suggested in its labeling, namely, "Patient lies in the Gynecological position on the examination table. The Speculum is inserted and antiseptic wet swabs are applied to the Os in order to remove any mucous. The Tenaculum Forceps used to seize the anterior lip is held in the left hand to steady the cervix and

*For failure to bear a label containing an accurate statement of the quantity of the contents, see Nos. 2453, 2457; failure to bear a label containing the name and place of business of the manufacturer, packer, or distributor, Nos. 2453, 2457; cosmetics, subject to the drug provisions of the Act, Nos. 2487–2489 (creams only), 2492.

bend it down. A Sound is introduced in order to establish the position, size and direction of the Uterine Cavity and also to determine the caliber of the cervical canal. The Speculum is then pressed posteriorily. It is most important to establish the length of the uterine cavity as the ring must be placed so as to be in contact with the upper end of the cavity. The bend in the cervical canal is straightened by pulling gently on the Tenaculum. Occasionally projecting folds in the mucous membrane of the cervical canal (especially in hypo-plastic uteri) causes some difficulty. This can be overcome by dilating the cervical canal with a Hegar's Dilator so that the introducing instrument can be passed after the dilation. This is quite easy if a No. 6 dilator can be passed. If No. 5 goes in easy it is not necessary to try No. 6 as this is wide enough for the introducing instrument. The latter is pushed in until the resistance of the fundus uteri is encountered. The ring which is compressible adapts itself to the canal while passing through it and resumes its circular shape when it gets into the uterine cavity. You can see this from an X-ray plate of the ring in situ. On withdrawing the introducing instrument, the walls of the uterus at the internal os detach the ring from the instrument and the latter comes out easily, leaving the ring behind. The Tenaculum Forceps are then removed, any blood clots are swabbed up, the Speculum is removed and a swab left on the vaginal entrance. * * * Care must be taken that the lower pole of the ring is within the cavity. * * * The ring may be left in for at least one year."

DISPOSITION: August 24, 1948. Default decree of condemnation and destruction.

DRUG REQUIRING CERTIFICATE OR RELEASE, FOR WHICH NONE HAD BEEN ISSUED

2452. Misbranding of penicillin sodium. U. S. v. Joseph A. Alverez (Proctor Laboratories). Plea of guilty. Sentence of 1 year in jail and fine of $1,000. Sentence subsequently modified to provide for suspended sentence of 1 year, revocation of fine, and probation for 2 years. (F. D. C. No. 24251. Sample Nos. 64198–H, 64199–H.)

INFORMATION FILED: May 27, 1948, District of New Jersey, against Joseph A. Alvarez, trading as Proctor Laboratories, at New York, N. Y.

ALLEGED SHIPMENT: On or about May 13, 1947, from the State of New Jersey into the State of New York.

LABEL, IN PART: "Penicillin Sodium Proctor * * * Proctor Laboratories * * * New York."

NATURE OF CHARGE: Misbranding, Section 502 (l), the article was represented as a drug composed wholly of penicillin sodium, a derivative of a kind of penicillin, and it was not from a batch with respect to which a certificate or a release had been issued pursuant to Section 507; Section 502 (a), the label statements "Lot No. 77 Expiration Date Oct–1–48" and "Lot No. 90 Expiration Date Oct. 1, 1948," were false and misleading, since they represented and suggested that the article had been certified in accordance with regulations, whereas the article had not been so certified; and, Section 502 (f) (1), the labeling of the article failed to bear adequate directions for use, in that there was no statement in the labeling of any condition, disease, or function for which the article was to be used, and in that there were no statements in the labeling of the dosage, methods, and duration of administration in accordance with which the article was to be used.

DISPOSITION: On July 26, 1948, a plea of guilty having been entered, the court sentenced the defendant to serve 1 year in jail and imposed a fine of $1,000. On August 2, 1948, after the defendant had served seven days in jail, the court modified the sentence to provide for a suspended sentence of 1 year in jail, for the revocation of the $1,000 fine, and for probation for 2 years.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF FAILURE TO BEAR ADEQUATE DIRECTIONS OR WARNING STATEMENTS*

2453. Action to enjoin and restrain the interstate shipment of a drug sometimes designated as "The Old Famous Sillard Cancer Remedy." U. S. v. Mrs. Bertha Stephens. Consent decree granting injunction. (Inj. No. 199.)

COMPLAINT FILED: Between September 24 and October 15, 1948, Eastern District of Tennessee, against Mrs. Bertha Stephens, North Chattanooga, Tenn.

NATURE OF CHARGE: That the defendant had been from time to time introducing and delivering for introduction into interstate commerce consignments of a drug consisting of a liquid containing small proportions of tincture of iron and potassium iodide, and sometimes designated by the name *The Old Famous Sillard Cancer Remedy;* that prior to about March 12, 1948, the drug was labeled as follows "The Old Famous Sillard Cancer Remedy Designed for the cure of Cancers or Ulcers and Stomach trouble of any kind. Directions One Tablespoonful before each meal. Made by Mrs. Bertha Stephens (North) Chattanooga, Tennessee"; that on or about March 12, 1948, the defendant caused the drug to be introduced into interstate commerce without any labeling; that the drug for many years past had been and was still intended for use in the treatment of cancers, ulcers, and stomach troubles of all kinds, but that labeling statements revealing its intended uses would be false and misleading, in that the drug was not efficaceous in the cure, mitigation, or treatment of such diseases; that any labeling statement representing or suggesting the use of the article as a drug would be false and misleading, in that it was without value in the cure, mitigation, treatment, or prevention of disease, or in beneficially affecting any function of the human body.

The complaint alleged further that prior to March 12, 1948, the drug was misbranded as follows:

Section 502 (a), the name "Cancer Remedy" and the statement "Designed for the cure of Cancers or Ulcers and Stomach trouble of any kind" were false and misleading, since the article would not be efficaceous in the cure of such diseases and conditions;

Section 502 (e) (2), the article was not designated solely by a name recognized in an official compendium and was fabricated from two or more ingredients, and its label failed to bear the common or usual name of each active ingredient;

Section 502 (f) (2), the labeling of the article failed to bear warnings against use in those pathological conditions where its use may be dangerous to health, in such manner and form as are necessary for the protection of users, in that the use of the article might be dangerous to the health of persons suffering from lung disease, chronic coughs, or goiter (thyroid diseases); and the labeling of the article failed to bear any warning against unsafe duration of administration, since it failed to bear a warning to discontinue the use of the article if a skin rash appeared.

The complaint alleged also that the article when introduced into interstate commerce on or about March 12, 1948, was misbranded as follows:

Section 502 (f) (1), the article failed to bear adequate directions for use for the purposes for which it was intended;

Section 502 (f) (2), the labeling of the article failed to bear adequate warnings against use in pathological conditions where its use may be dangerous to health, and warnings against unsafe duration of administration, in such manner and form as are necessary for the protection of users;

Section 502 (b) (1), the article failed to bear a label containing the name and place of business of the manufacturer, packer, or distributor;

Section 502 (b) (2), the article failed to bear a label containing an accurate statement of the quantity of the contents in terms of weight, measure, or numerical count;

Section 502 (e) (2), the article failed to bear a label declaring the common or usual name of each active ingredient.

PRAYER OF COMPLAINT: That the defendant be restrained and enjoined during the pendency of the action, and permanently, from shipping the above-mentioned drug in interstate commerce.

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*See also No. 2452.

DISPOSITION: October 15, 1948. The defendant having consented to the entry of a decree, an order was entered enjoining the defendant from directly or indirectly introducing or delivering for introduction into interstate commerce the above-mentioned product, which was misbranded within the meaning of Sections 502 (a), 502 (f) (1) and (2), 502 (e) (2), and 502 (b) (1) and (2).

2454. Misbranding of Formalon Cream. U. S. v. Daniel Platt (Formalon Company). Plea of guilty. Defendant fined $3,000, given suspended sentence of 3 years in jail, and placed on probation for 3 years. (F. D. C. No. 21466. Sample Nos. 70802–H, 12947–K, 12948–K.)

INFORMATION FILED: January 23, 1948, Southern District of New York, against Daniel Platt, trading as the Formalon Co., New York, N. Y.

ALLEGED SHIPMENT: From the State of New York into the States of Delaware, California, Pennsylvania, Massachusetts, and New Jersey. The product was shipped during March and April 1946, and January and March 1947, and a circular letter was shipped during March, April, and November 1946, and January and March 1947.

PRODUCT: Analysis disclosed that the product consisted of a pale-yellow semisolid containing 27.2 mg. diethylstilbestrol in each 2 ounces. Examination showed that the circular letter contained a number of statements relating to the efficacy of the product for the development of the breasts and pictures of women purportedly before and after the use of the product.

LABEL, IN PART: "Directions Apply ½ teaspoon of Formalon daily to each breast and massage gently at bedtime, or as otherwise directed by physician. Formalon Cream."

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements and pictures appearing in the circular letter were false and misleading. The statements and pictures represented and suggested that the article would be effective to develop the breasts of women, whereas it would not be effective for such purposes.

Further misbranding, Section 502 (a), the before and after pictures designated "Case 5469" and the statement underneath "showing breast growth produced after using Formalon 8 weeks" and the before and after pictures designated "Case 1721" and the statement underneath "showing breast growth produced after 12 weeks of applying Formalon Cream," appearing in the circular letter, were false and misleading. The pictures and statements represented and suggested that the pictures were pictures of women which had been taken before and after treatment with the article, whereas the pictures were pictures of women which had been taken before and after treatment with another drug.

Further misbranding, Section 502 (f) (1), the labeling of the article failed to bear adequate directions for use, since the directions which appeared on the label failed to reveal the conditions for which the article was to be used.

DISPOSITION: August 4, 1948. A plea of guilty having been entered, the court fined the defendant $3,000 and sentenced him to serve 3 years in jail. The jail sentence was suspended and the defendant was placed on probation for 3 years, conditioned that he should not directly or indirectly engage in the sale of drugs or food preparations of any kind, nature, or description.

2455. Misbranding of Emerson's Medicine, Emerson's K-A-C Cough Syrup, and Emerson's Lightning Liniment. U. S. v. 7 Bottles, etc. (F. D. C. No. 24854. Sample Nos. 22544–K to 22546–K, incl.)

LIBEL FILED: On or about May 27, 1948, Southern District of Texas.

ALLEGED SHIPMENT: By the Emerson Medicine Co., from Kansas City, Mo.; the products were shipped on or about April 8, 1948, and a number of circulars were shipped on or about January 5, 1948.

PRODUCT: 7 12-ounce bottles of *Emerson's Medicine*, 7 2-ounce bottles of *Emerson's K-A-C Cough Syrup*, and 18 2-ounce bottles of *Emerson's Lightning Liniment* at Houston, Tex., together with 32 circulars entitled "Emerson's Medicine," which were enclosed with the syrup and wrapped around the bottles of the liniment, and 50 circulars entitled "Emerson's Medicine is Mother Nature's Own Laxative Medicine," which were shipped separately from the products.

Analyses disclosed that the *Emerson's Medicine* consisted of water and extracts of plant drugs, including a laxative drug, together with a small propor-

tion of sodium salicylate; and that the *Emerson's K-A-C Cough Syrup* consisted essentially of sugar, menthol, camphor, ammonium chloride, potassium antimony tartrate, alcohol, and water.

NATURE OF CHARGE: *Emerson's Medicine.* Misbranding, Section 502 (a), the following statements in the labeling of the article were false and misleading, since they represented and suggested that the other ingredients named are adjuvants to the laxative action of aloes and that the article was effective to fulfill the promises of benefit stated and implied, whereas the other ingredients named are not adjuvants to the laxative action of aloes and the article was not effective to fulfill the promises of benefit stated and implied: (Carton and bottle label) "Active Ingredient: Curacao Aloes to which is added as Bitter Adjuvants Honduras Sarsaparilla, Poke Root, Dandelion Root, Prickly Ash Bark, Liverwort Leaves, Mandrake Root, Gential Root, Stillingia, Burdock and Yellow Dock"; (circular entitled "Emerson's Medicine") "Carefully extracted juices from these well known roots and herbs according to Dr. Ray's specifications are added to the curacao aloes as bitter adjuvants. We believe that the combination of these ingredients is what has made Emerson's Medicine famous nationwide . . . Feel better . . . work better . . . eat better . . . sleep better"; and (circular entitled "Emerson's Medicine is Mother Nature's Own Laxitive Medicine") "Tonic in action . . . Carefully extracted juices from these well known roots and herbs according to Dr. Ray's specifications are added to the Curacao aloes as bitter adjuvants. We believe that the combination of these ingredients is what has made Emerson's Medicine famous nationwide . . . Feel better . . . work better . . . eat better . . . sleep better . . . Health Brings Success. Healthy men and women stand a much better chance of gaining success in this busy world. Nothing is so valuable as physical fitness! Steady Nerves, firm muscles, a painless body, all make the quick active brain. Develop that pep and punch so necessary to overcome obstacles. Bring success to social and business life."

Further misbranding, Section 502 (f) (2), the labeling of the *Emerson's Medicine*, failed to bear such adequate warnings against unsafe duration of administration, in such manner and form as are necessary for the protection of users, since the article was essentially a laxative and its labeling failed to warn that frequent or continued use may result in dependence on a laxative to move the bowels.

Emerson's K-A-C Cough Syrup. Misbranding, Section 502 (a), the label statement "Relieves * * * colds, spasmodic croup * * * sore throat * * * congestion of upper respiratory organs, whooping cough" were false and misleading, since the article was not effective to relieve such conditions.

Emerson's K-A-C Cough Syrup and *Emerson's Lightning Liniment.* Misbranding, Section 502 (a), certain statements in circulars enclosed with the syrup and wrapped around bottles of the liniment, were false and misleading. These circulars contained representations regarding *Emerson's Medicine* which were similar to those in the circulars accompanying that product.

DISPOSITION: July 9, 1948. Default decree of condemnation and destruction.

2456. Misbranding of Sanite Ergot and Apiol Compound. U. S. v. 30 Dozen Boxes * * *. (F. D. C. No. 24748. Sample No. 345-K.)

LIBEL FILED: On or about April 28, 1948, Northern District of Georgia.

ALLEGED SHIPMENT: On or about March 2, 13, and 16, 1948, by the American Pharmaceutical Co., Inc., from New York, N. Y.

PRODUCT: 30 dozen boxes, each containing 25 capsules, of *Sanite Ergot and Apiol Compound* at Atlanta, Ga.

NATURE OF CHARGE: Misbranding, Section 502 (f) (1), the labeling of the article failed to bear adequate directions for use, since its labeling failed to reveal the conditions for which the drug was to be taken.

DISPOSITION: June 15, 1948. Default decree of condemnation and destruction.

2457. Misbranding of potassium soap. U. S. v. 11 Tubes * * *. (F. D. C. No. 24378. Sample No. 22351—K.

LIBEL FILED: March 15, 1948, Western District of Louisiana.

ALLEGED SHIPMENT: On or about January 24, 1948, from Dallas, Tex., by F. H. Jordan.

PRODUCT: 11 unlabeled tubes of *potassium soap* at Monroe, La. Analysis showed that the product consisted of a viscous solution of a potassium soap containing potassium iodide and crystal violet.

NATURE OF CHARGE: Misbranding, Section 502 (b) (1), the article failed to bear a label containing the name and place of business of the manufacturer, packer, or distributor; Section 502 (b) (2), it failed to bear a label containing an accurate statement of the quantity of the contents; Section 502 (e) (2), it was fabricated from two or more ingredients, and its label failed to bear the common or usual name of each active ingredient; and, Section 502 (f) (1), the labeling of the article failed to bear adequate directions for use.

DISPOSITION: October 7, 1948. Default decree of condemnation and destruction.

2458. Misbranding of eucalyptus oil liniment and inhalers. U. S. v. 124 Bottles, etc. (F. D. C. No. 24873. Sample No. 19602–K.)

LIBEL FILED: June 8, 1948, Southern District of Ohio.

ALLEGED SHIPMENT: On or about May 5 and 12, 1948, by E. N. Golden, from Detroit, Mich.

PRODUCT: 124 bottles of *eucalyptus oil liniment* and 288 *inhalers* at Cincinnati, Ohio, together with 200 circulars entitled "Gold–N–Ray Eucalyptus Compound." Sales of the product were made on the basis of lectures given at the store of the consignee by Mrs. Edward N. Golden, also known as Dorothy D. Dickstein on behalf of Edward N. Golden, the distributor. The charge of misbranding under Section 502 (f) (1) reported herein is based on her oral representations.

Examination showed that the *eucalyptus oil liniment* consisted of volatile oils, including eucalyptus and peppermint oils, approximately 28 percent, and nonsaponifiable oil such as petroleum oil, approximately 72 percent; and that the inhaler consisted of a glass tube open at both ends, containing a wad of cotton surrounded by paper and held in place by perforated corks.

LABEL, IN PART: (Bottle) "Gold–N–Ray Eucalyptus Oil Liniment Buy from your druggist or direct from The Golden Boy Dist. Co., * * * Brooklyn, New York"; (inhaler) "Gold–N–Ray Inhaler Gold–N–Boy Dist. Co."

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements in the circulars were false and misleading. These statements represented and suggested that the *Gold–N–Ray Eucalyptus Compound* was a refined and improved distillate from eucalyptus leaves; that it possessed the power of producing or maintaining health and energy; that it exhibits miraculous properties; that in vapor form it would cleanse and disinfect the air, banish malaria, yellow fever, and epidemic fever; that it would play an important part in keeping one well and in keeping the body sound, sturdy, and safe against infection and many common ailments; that it was a powerful antiseptic; that it was efficaceous in asthma and catarrhal conditions; and that it would supply the need for stimulation and disinfection. The article was not a refined and improved distillate from eucalyptus leaves but consisted largely of a nonsaponifiable oil, such as petroleum oil, with a relatively small proportion of volatile oils including eucalyptus oil; and it would not fulfill the promises of benefit stated and implied.

Further misbranding, Section 502(a), the bottle label statement "Eucalyptus Oil Liniment" was false and misleading, since the article did not consist of eucalyptus oil; and, Section 502 (f) (1), the labeling of the article failed to bear adequate directions for use in the treatment of hay fever, sinus affections, colds, sore throat, asthma, neuritis, arthritis, and rheumatism, which were the diseases, symptoms, and conditions for which the article was offered in its advertising, disseminated and sponsored by or on behalf of the manufacturer, packer, and distributor.

DISPOSITION: September 3, 1948. Default decree of condemnation and destruction.

2459. Misbranding of Williams Yukol and Williams Yukol Inhaler. U. S. v. 107 Bottles, etc. (F. D. C. No. 24695. Sample Nos. 10215–K, 10216–K.)

LIBEL FILED: March 31, 1948, District of New Jersey.

ALLEGED SHIPMENT: On or about February 24, 1948, by the Newman Products Co., from New York, N. Y.

PRODUCT: 107 4-ounce bottles and 71 8-ounce bottles of *Williams Yukol* and 150 *Williams Yukol Inhalers* at Plainfield, N. J., together with a number of circulars entitled "Yukol Daily Relief" and a number of instruction sheets entitled "Yukol—A counter irritant." Examination showed that the *Williams Yukol* consisted of a kerosene solution of volatile oils, including eucalyptus oil, peppermint oil, thymol, and methyl salicylate, and that it contained no petrolatum. The *Williams Yukol Inhaler* consisted of an open glass tube, constricted on one end. Each end was closed with a cork stopper having a hole bored in the center. Between the two corks was a small wad of cotton.

NATURE OF CHARGE: Misbranding, Section 502 (a), the statement on the label of the *Williams Yukol* "containing eucalyptus oil, thymol, menthol, oil of camphor, oil of peppermint, petrolatum" was false and misleading, since the *Yukol* contained among other ingredients, methyl salicylate and kerosene, and no petrolatum; and the following statements in the labeling of the *Yukol* were false and misleading, since a mixture of *Yukol*, honey, and lemon juice is not effective in the treatment of coughs, and the *Yukol* was not effective as a liniment for the relief of the symptoms and muscular aches and pains associated with, and caused by, rheumatism, arithritis, lumbago, sciatica, and neuritis: (Circular) "Cough Syrup ½ teaspoonful Yukol, 8 oz. honey, juice of 1 lemon. Heat honey, mix well with Yukol and lemon"; (instruction sheet) "Yukol—As a Liniment For the relief of the symptoms and the muscular pains and aches associated with and caused by rheumatism, arthritis, lumbago, sciatica and neuritis."

Further misbranding, Section 502 (f) (1), the labeling of the article failed to bear adequate directions for use in the treatment of chest colds, bronchitis, mastoids, mastoiditis, cramped or stiffened condition of the joints, sore throat, sinus condition, and rheumatic ailments, which were the diseases and conditions for which the articles were offered in advertising disseminated and sponsored by the distributor of the articles, Fausto R. Yznaga.

DISPOSITION: May 11, 1948. Default decree of condemnation and destruction.

2460. Action to enjoin and restrain the interstate shipment of a device referred to as "The Master Cell," "Solar Crystal Matrix Battery," and "Master Cell Matrix." U. S. v. John C. Brown, Gustave Goerner, Merrill Sampson, Kenneth J. Gleason, and J. H. Gildard (The Goernersome Brownii Foundation Cell Laboratories). Consent decree granting injunction. (Inj. No. 202.)

COMPLAINT FILED: September 27, 1948, District of Massachusetts, against John C. Brown, Gustave Goerner, Merrill Sampson, Kenneth J. Gleason, and J. H. Gildard, as individuals and as associates under the name of The Goernersome Brownii Foundation Cell Laboratories, doing business at Middleboro, Mass.

NATURE OF CHARGE: That the defendants were introducing and delivering for introduction into interstate commerce a device consisting of a concrete disc made of sand, cement, and water containing the common protozoan paramecium, and referred to as "The Master Cell," "Solar Crystal Matrix Battery," and "Master Cell Matrix." The device was misbranded within the meaning of Section 502 (f) (1), in that its labeling failed to bear adequate directions for use since the labeling bore no directions for use in all conditions for which the device was intended to be used and for which it was prescribed, recommended, or suggested in oral representations made by or on behalf of the defendants, namely, as a preventive and treatment of respiratory and intestinal diseases of poultry and a general treatment of diseases in man and lower animals.

PRAYER OF COMPLAINT: That the defendants be perpetually enjoined from commission of the acts complained of.

DISPOSITION: October 1, 1948. The defendants having consented to the entry of a decree, the court issued an order enjoining them from directly or indirectly introducing or delivering for introduction into interstate commerce the device in question, which was misbranded within the meaning of Section 502 (f) (1).

2461. Misbranding of Spectro-Chrome. U. S. v. 1 Device * * * (and 4 other seizure actions). Answers filed by claimants denying Government's right to seize devices; claimants' answers ordered stricken and default decrees of condemnation and destruction entered. (F. D. C. Nos. 16828, 16830, 16911, 17280, 18137. Sample Nos. 1146–H, 4171–H, 14657–H, 14695–H, 17267–H.)

LIBELS FILED: July 19 and 25, September 10, and November 27, 1945, Eastern District of Michigan.

ALLEGED SHIPMENT: Between the approximate dates of May 22 and November 5, 1945, by the Dinshah Spectro-Chrome Institute, from Newfield, N. J.

PRODUCT: 5 *Spectro-Chrome* devices at Flat Rock, Detroit, and Fraser, Mich. The construction and appearance of each device was essentially the same as the device involved in notices of judgment on drugs and devices, No. 2098.

Three of the devices were accompanied by one or more of the following pieces of printed and graphic matter: "Spectro-Chrome Home Guide," "Favorscope for 1945," "Rational Food of Man," "Key to Radiant Health," "Request for Enrollment as Benefit Student," "Auxiliary Benefit Notice — Make Your Own Independent Income as Our Introducer," "Spectro-Chrome General Advice Chart for the Service of Mankind — Free Guidance Request," "Certificate of Benefit Studentship," "Spectro-Chrome — December 1941 — Scarlet," and "Spectro-Chrome — March 1945 — Yellow."

NATURE OF CHARGE: Misbranding, Section 502 (a), (2 devices) the following statements in the labeling of the devices "Dinshah Spectro-Chrome * * * Visible Spectrum Color Projector * * * This Spectro-Chrome Projector * * * is a Benefit granted to an Affiliate (of Dinshah Spectro-Chrome Institute a * * * Health Corporation * * *) * * * It is presented for self-use and self-verification" were false and misleading, since such statements represented and suggested that the device was capable of restoring, maintaining, or otherwise favorably influencing the health of the user, whereas the device was incapable of restoring, maintaining, or otherwise favorably affecting the health of the user; and the use of colored light would have no effect on health. The labeling of the other three devices bore false and misleading curative and therapeutic claims substantially the same as the labeling of the device involved in notices of judgment on drugs and devices, No. 2098.

Further misbranding, Section 502 (f) (1), (1 device) the labeling failed to bear adequate directions for use, since it bore no directions for use.

DISPOSITION: Florence L. Shuman, Flat Rock, Mich., Rosa Campiglio, Blanche DeWitt, and James H. Stevens, Detroit, Mich., and Martha Kollmorgan, Fraser, Mich., appeared as claimants and filed answers to the libels. The cases were subsequently consolidated for trial. A motion was filed on behalf of the Government to strike all impertinent, immaterial, incoherent, and surplus matter from the answers. This motion was granted on November 27, 1945. Thereafter, the claimants moved to dismiss the libels, which motion was denied. The Government filed motions for an order directing the claimants to file stipulation for costs and for an order requiring the claimants to make further and more perfect answers to the libels. The Government's motions were granted, after hearing, on February 25, 1948.

On September 22, 1948, the court ordered that each claimant post security for costs; that the document "Further and More Perfect Answer," filed on behalf of the claimants, be stricken from the record; that any answer filed on behalf of the claimants conform to the requirements of Admiralty Rule No. 26; and that the failure of the claimants to file such answer by October 1, 1948, should effect a default. The claimants failed to file the required answer, or to post security for costs, by October 1, and accordingly an order of default was made on that date and judgment was entered, condemning the devices and their labeling and ordering their destruction.

DRUG ACTIONABLE BECAUSE OF CONTAMINATION WITH FILTH

2462. Adulteration of Hood-Lax. U. S. v. Hood Products Corporation, Cal-Par Corporation, and Charles H. Fingerhood. Pleas of guilty. Total fine of $4,000 ($3,500 of fine applicable to another product). (F. D. C. No. 24046. Sample No. 6516–H.)

INFORMATION FILED: March 17, 1948, Southern District of New York, against the Hood Products Corporation and the Cal-Par Corporation, New York, N. Y., and Charles H. Fingerhood, president and treasurer of the corporation.

ALLEGED SHIPMENT: On or about January 31, 1946, from the State of New York into the State of New Jersey.

NATURE OF CHARGE: Adulteration, Section 501 (a) (1), the article consisted in part of a filthy substance, i. e., larvae, insect fragments, and a rodent hair fragment; and, Section 501 (a) (2), it had been prepared under insanitary conditions whereby it may have become contaminated with filth.

The information alleged also that another product known as *Cal-Par* was adulterated under the provisions of the law applicable to foods, as reported in notices of judgment on food.

DISPOSITION: October 8, 1948. Pleas of guilty having been entered, the court imposed a total fine of $4,000 against the defendants jointly and severally, of which $500 was attributable to count 1 of the information relating to the *Hood-Lax*.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF DEVIATION FROM OFFICIAL OR OWN STANDARDS

2463. Adulteration of aminophylline. U. S. v. Herman Edward Maurry (H. E. Maurry Biological Co.). Plea of nolo contendere. Fine, $250. (F. D. C. No. 24271. Sample No. 86016–H.)

INFORMATION FILED: August 2, 1948, Southern District of California, against Herman Edward Maurry, trading as the H. E. Maurry Biological Co., Los Angeles, Calif.

ALLEGED SHIPMENT: On or about December 13, 1946, from the State of California into the State of Colorado.

LABEL, IN PART: "Aminophylline U. S. P. XII * * * (Theophylline Ethylenediamine) * * * For Intravenous Injection."

NATURE OF CHARGE: Adulteration, Section 501 (b), the article purported to be and was represented as "Theophylline Ethylenediamine Injection (Aminophylline Ampuls)," a drug the name of which is recognized in the United States Pharmacopoeia, and its quality and purity fell below the official standard since it contained undissolved material which could be detected readily without magnification when tested in accordance with the method prescribed by the standard; and the difference in the quality and purity of the article from the standard was not plainly stated, or stated at all, on its label.

DISPOSITION: September 20, 1948. A plea of nolo contendere having been entered, the court imposed a fine of $250.

2464. Adulteration of sodium iodide ampuls. U. S. v. 33,447 Ampuls, etc. (F. D. C. No. 24862. Sample Nos. 10561–K, 10567–K, 10572–K.)

LIBEL FILED: June 1, 1948, Eastern District of New York.

ALLEGED SHIPMENT: On or about March 30 and April 2 and 13, 1948, from Somerville, N. J., and Montgomery, Ala., by Veterans Administration Supply Depots. (These were return shipments.)

PRODUCT: 38,222 20-cc. ampuls and 2,375 10-cc. ampuls of *sodium iodide* at Long Island City, N. Y.

NATURE OF CHARGE: Adulteration, Section 501 (b), the article purported to be and was represented as "Sodium Iodide Ampuls," a drug the name of which is recognized in the National Formulary, an official compendium, and its quality and purity fell below the official standard, since it was contaminated with undissolved material.

DISPOSITION: July 28, 1948. Default decree of condemnation and destruction.

2465. Adulteration and misbranding of Aquadiol. U. S. v. 48 Vials * * *. (F. D. C. No. 24904. Sample Nos. 255–K, 274–K.)

LIBEL FILED: On or about June 29, 1948, Northern District of Georgia.

ALLEGED SHIPMENT: On or about January 31 and May 10, 1948, by the National Drug Co., from Philadelphia, Pa.

PRODUCT: 48 25-cc. vials of *Aquadiol* at Atlanta, Ga.

NATURE OF CHARGE: Adulteration, Section 501 (c), the strength of the article differed from that which it was represented to possess, i. e., 0.22 milligram of alpha estradiol per cubic centimeter.

Misbranding, Section 502 (a), the label statement "per cc. 0.22 mg. alpha Estradiol" was false and misleading as applied to the article, which contained less than 0.13 milligram of alpha estradiol per cubic centimeter.

DISPOSITION: July 30, 1948. Default decree of condemnation and destruction.

2466. Adulteration and misbranding of distilled water. U. S. v. Lincoln Laboratories, Inc. Plea of nolo contendere. Fine, $750. (F. D. C. No. 23265. Sample Nos. 56546–H, 86728–H.)

INFORMATION FILED: December 18, 1947, Southern District of Illinois, against Lincoln Laboratories, Inc., Decatur, Ill.

ALLEGED SHIPMENT: On or about July 12, 1946, and May 9, 1947, from the State of Illinois into the State of Missouri.

NATURE OF CHARGE: Adulteration, Section 501 (b), the article purported to be "Water for Injection," a drug the name of which is recognized in the United States Pharmacopoeia, an official compendium, and its quality and purity fell below the official standard since it contained undissolved material which could be detected readily without magnification when examined in the manner described in the standard and since a portion of the article contained pyrogens and also was not sterile, but was contaminated with viable bacteria; and the difference in quality and purity of the article from the standard was not plainly stated, or stated at all, on its label.

Misbranding, Section 502 (a), the statement on the label of 1 shipment of the article "The contents of this vial consists of sterile, * * * pyrogen free water" was false and misleading, since the article involved in this shipment was not sterile but was contaminated with viable bacilli and contained pyrogens.

DISPOSITION: August 23, 1948. A plea of nolo contendere having been entered, the court imposed a fine of $750.

2467. Adulteration of water for injection. U. S. v. 10 Boxes * * *. (F. D. C. No. 24886. Sample No. 4379–K.)

LIBEL FILED: June 14, 1948, District of Maine.

ALLEGED SHIPMENT: On or about April 21, 1948, by Brewer & Co., Inc., from Worcester, Mass.

PRODUCT: 10 boxes, each containing 25 ampuls, of *water for injection* at Portland, Maine.

LABEL, IN PART: "20-cc. Plus Water for Injection."

NATURE OF CHARGE: Adulteration, Section 501 (b), the article purported to be and was represented as "Water for Injection," a drug the name of which is recognized in the United States Pharmacopoeia, an official compendium, and its quality and purity fell below the official standard since it was contaminated with undissolved material.

DISPOSITION: July 13, 1948. Default decree of condemnation and destruction.

2468. Adulteration and misbranding of peppermint leaves, belladonna leaves, and boneset. U. S. v. Allaire, Woodward & Co. and Norvin J. Busch. Pleas of nolo contendere. Fines of $2,300 and costs against company and $200 and costs against individual. (F. D. C. No. 24269. Sample Nos. 2443–K, 6415–K, 10275–K, 16817–K, 18026–K to 18028–K, incl., 18864–K, 19241–K, 19720–K, 27210–K.)

INFORMATION FILED: July 14, 1948, Southern District of Illinois, against Allaire, Woodward & Co., a corporation, Peoria, Ill., and Norvin J. Busch, president and treasurer.

ALLEGED SHIPMENT: Between the approximate dates of June 28, 1946, and December 18, 1947, from the State of Illinois into the States of West Virginia, New York, Wisconsin, Indiana, Ohio, and Missouri.

NATURE OF CHARGE: *Peppermint leaves.* Adulteration, Section 501 (d) (2), a product containing stramonium had been substituted for *peppermint leaves.* Misbranding, Section 502 (a), the label statements "Peppermint Leaves * * * it is Peppermint Leaves only" were false and misleading, since the article did not consist solely of *peppermint leaves* but also contained stramonium.

Boneset. Adulteration, Section 501 (d) (2), a product containing stramonium had been substituted for "Boneset * * * N. F." Misbranding, Sec-

tion 502 (a), the label statement "Boneset * * * N. F." was false and misleading, since the article did not consist of *boneset* which conformed to the requirements of the National Formulary.

Powdered belladonna leaf. Adulteration, Section 501 (d) (2), a product containing stramonium had been substituted for *belladonna leaf*. Misbranding, Section 502 (a), the label statement "Belladonna Leaf * * * U. S. P." was false and misleading, since the article did not consist of *belladonna leaf* which conformed to the requirements of the United States Pharmacopoeia, but did consist of a mixture of *belladonna leaf* and stramonium.

DISPOSITION: July 28, 1948. Pleas of nolo contendere having been entered, the court imposed fines of $2,300 and costs against the corporation and $200 and costs against the individual.

2469. Adulteration of wild cherry bark. U. S. v. 1 Bag * * *. (F. D. C. No. 24727. Sample No. 10531–K.)

LIBEL FILED: April 16, 1948, District of New Jersey.

ALLEGED SHIPMENT: On or about December 15, 1947, by Ward G. Phillips, from North Wilkesboro, N. C.

PRODUCT: 1 bag of *wild cherry bark* at Jersey City, N. J.

LABEL, IN PART: "Thin Rossed Wild Cherry Bark."

NATURE OF CHARGE: Adulteration, Section 501 (b), the article purported to be and was represented as "Wild Cherry Bark," a drug the name of which is recognized in the National Formulary, an official compendium, and its quality and purity fell below the official standard since it was moldy and insect bored.

DISPOSITION: May 25, 1948. Default decree of condemnation and destruction.

2470. Adulteration and misbranding of prophylactics. U. S. v. 53 Gross * * *. (F. D. C. No. 24715. Sample No. 4025–K.)

LIBEL FILED: April 8, 1948, District of Massachusetts.

ALLEGED SHIPMENT: On or about February 24, 1948, by the Duratex Corp., from Newark, N. J.

PRODUCT: 53 gross of *prophylactics* at Boston, Mass. Examination of samples showed that 2.1 percent were defective in that they contained holes.

LABEL, IN PART: "Arab Prophylactics Genuine Latex."

NATURE OF CHARGE: Adulteration, Section 501 (c), the quality of the article fell below that which it purported and was represented to possess.

Misbranding, Section 502 (a), the label statement "Prophylactics" was false and misleading as applied to an article containing holes.

DISPOSITION: August 31, 1948. Default decree of condemnation and destruction.

2471. Adulteration and misbranding of prophylactics. U. S. v. 45 Gross * * *. (F. D. C. No. 25674. Sample No. 45622–K.)

LIBEL FILED: September 28, 1948, Eastern District of Missouri.

ALLEGED SHIPMENT: On or about August 25, 1948, by the World Merchandise Exchange & Trading Co., Inc., from New York, N. Y.

PRODUCT: 45 gross of *prophylactics* at St. Louis, Mo. Examination of samples showed that 7.4 percent were defective in that they contained holes.

LABEL, IN PART: "Tetratex Manufactured By L. E. Shunk Latex Prod. Inc., Akron, Ohio."

NATURE OF CHARGE: Adulteration, Section 501 (c), the quality of the article fell below that which it purported and was represented to possess.

Misbranding, Section 502 (a), the label statements "Prophylactic," "Prophylactics * * * has been electronically tested and hermetically sealed in metal for your protection," and "Electronically Tested * * * hermetically sealed in individual metal containers for your protection" were false and misleading as applied to an article containing holes.

DISPOSITION: October 22, 1948. Default decree of condemnation and destruction.

2472. Adulteration and misbranding of prophylactics. U. S. v. 43 Dozen * * *. (F. D. C. No. 24486. Sample No. 21169–K.)

LIBEL FILED: March 16, 1948, Western District of Missouri.

ALLEGED SHIPMENT: On or about February 6, 1948, by W. H. Reed & Co., Inc., from Atlanta, Ga.

PRODUCT: 43 dozen *phrophylactics* made from animal membrane at Kansas City, Mo. Examination of the articles showed that 8.3 percent were defective in that they contained holes.

LABEL, IN PART: "Black and Gold Manufactured by Olympia Laboratories."

NATURE OF CHARGE: Adulteration, Section 501 (c), the quality of the article fell below that which it purported and was represented to possess.

Misbranding, Section 502 (a), the label statement "For the prevention of contagious diseases" was false and misleading as applied to an article containing holes.

DISPOSITION: May 26, 1948. W. H. Reed & Co., Inc., claimant, having consented to the entry of a decree, judgment of condemnation was entered and the product was ordered released under bond for segregation and destruction of the unfit portion, under the supervision of the Federal Security Agency. After the segregation operations were begun, it was determined by the claimant that further work was not justified. In accordance with the claimant's desire, the entire lot was destroyed.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF FALSE AND MISLEADING CLAIMS

DRUGS FOR HUMAN USE*

2473. Misbranding of Dr. Peter's Kuriko. U. S. v. 6 Dozen Bottles, etc. Tried to the jury. Decree of condemnation and destruction. Affirmed on appeal. (F. D. C. No. 11219. Sample No. 55919–F.)

LIBEL FILED: December 10, 1943, Western District of Washington; transferred to Eastern District of Wisconsin on April 18, 1944.

ALLEGED SHIPMENT: On or about October 26, 1943, by Dr. Peter Fahrney & Sons Co., from Chicago, Ill.

PRODUCT: 6 dozen bottles of *Dr. Peter's Kuriko* and a number of circulars entitled "Dr. Peter's Kuriko" at Poulsbo, Wash. Examination showed that the product consisted of a sweetened solution in water and alcohol of extracts of plant drugs, including a laxative drug such as senna.

LABEL, IN PART: "Alcohol 14 per cent Prepared from the following ingredients: Senna, Fennel, Mandrake Root, Peppermint, Spearmint, Mountain Mint, Horsemint, Sarsaparilla, Sassafras, Hyssop, Blessed Thistle, Dittany, Ground Ivy, Johnswort, Lemon Balm, Sage, Spikenard, Yarrow."

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements and pictures on the bottle label and in the circular entitled "Dr. Peter's Kuriko" were false and misleading. It was charged that these statements and pictures represented and suggested that the article would be effective in the cure, mitigation, or treatment of functional constipation, nervousness, indigestion, upset stomach, headaches, loss of sleep and appetite, foul breath, coated tongue, general feeling of ill health, general malaise, and common colds, and that the product when taken as directed would not fulfill the promises of benefit stated and implied.

DISPOSITION: The case having been transferred to the Eastern District of Wisconsin for trial, Dr. Peter Fahrney & Sons Co., claimant, filed a motion to transfer the case to the Northern District of Illinois. The motion was argued on May 31, 1944, and the court handed down the following opinion denying the claimant's motion:

F. RYAN DUFFY, *District Judge:* "The claimant, an Illinois corporation, with its principal place of business at Chicago, moves for an order transferring this proceeding to the United States District Court for the Northern District of Illinois, Eastern Division, asserting that trial in this district would cause it undue hardship, prevent it from making proper proof of its defenses, and cause great inconvenience to its witnesses, even preventing some of them, whose testimony would be material, from attending the trial.

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*See also Nos. 2452–2455, 2458, 2459, 2461, 2465, 2466, 2468, 2470–2472.

"This proceeding is under the Federal Food, Drug and Cosmetic Act (52 Stat. Sec. 1040, 21 U. S. C. A., Sec. 301 et seq.), and was commenced on December 10, 1943, in the United States District Court for the Western District of Washington, Northern Division. Claimant was allowed to intervene by that court, and on April 18, 1944, on claimant's motion, an order was entered transferring the proceeding to this court 'for trial,' the district thereof being 'a District of reasonable proximity to the intervenor's (claimant's) principal place of business.' As claimant had moved the district court in Washington that transfer be ordered 'to the United States District Court for the Northern District of Illinois, Eastern Division, or to a United States District Court within reasonable proximity of Chicago, Illinois, the principal place of business of said intervenor,' its present motion constitutes a second attempt to secure transfer to the district court in Illinois.

"In connection with the right to removals and the exercise thereof, Sec. 334 (a) of the act provides:

> . . . the proceeding pending or instituted shall, on application of the claimant seasonably made, be removed for trial to any district agreed upon by stipulation between the parties, or, in case of failure to so stipulate within a reasonable time, the claimant may apply to the court of the district in which the seizure has been made, and such court (after giving the United States attorney for such district reasonable notice and opportunity to be heard) shall by order, unless good cause to the contrary is shown, specify a district of reasonable proximity to the claimant's principal place of business, to which the case shall be removed for trial.

"Manifestly, claimant's application for removal to the district court in Illinois was not granted by the district court in Washington, because the same would not have been and is not authorized. In the absence of stipulation between the parties the power of removal of the court of original jurisdiction is limited and restricted. Such court is required to order removal to 'a district of reasonable proximity to the claimant's principal place of business.' Accordingly, it would have been beyond the power of the district court in Washington to have removed this proceeding to the designated district court in Illinois.

"The power of removal is exclusively conferred under the act upon the court of original jurisdiction, barring, of course, the existence of a stipulation of the parties on the subject. As the latter element does not obtain in the instant situation, this court has no power to grant the requested removal. In other words, the right to removal is completely exhausted and no longer exists in this proceeding.

"Claimant contends, however, that this court may order the requested removal under Sec. 334 (f) (2) of the act, which provides:

> The court to which such case was removed shall have the powers and be subject to the duties, for the purposes of such case, which the court from which removal was made would have had, or to which such court would have been subject, if such case had not been removed.

"As pointed out, the proceeding was removed, pursuant to the statute, to this court 'for trial' and not for any other purpose. The language of the act last quoted is consistent with such limitation and expressly negatives any power in this court to grant further removal on application. A claimant in proceedings of this nature is limited to a single application for removal which must be made to the court of original jurisdiction. My conclusions have complete support in the legislative history of the controlling statutory provisions.

"An order denying claimant's motion will be entered."

On June 7, 8, 11, and 12, 1945, the case was tried to a jury, which returned a special verdict in favor of the Government. The claimant thereupon filed a motion for judgment in its favor, notwithstanding the verdict and also moved for a new trial in the event of denial of the former. The claimant's motions were denied. The Government having moved for judgment on January 22, 1946, the court granted such motion and ordered the product condemned and destroyed.

The claimant having appealed on January 2, 1947, the Circuit Court of Appeals for the 7th Circuit handed down the following opinion, affirming the district court:

MAJOR, *Circuit Judge:* "This is an appeal from a decree entered January 22, 1946, in a proceeding commenced by the filing of a Libel Information under the Federal Food, Drug, and Cosmetic Act, 21 U. S. C. A. 301 *et seq.*, which prayed the condemnation of an article called Dr. Peter's Kuriko, on the ground

that it was misbranded when in interstate commerce. The *res* involved is a medicine manufactured by Dr. Peter Fahrney & Sons Company, referred to as the claimant which intervened and defended the action. The cause was tried to a jury and a special verdict was returned which constitutes the basis for the decree in controversy.

"The libel as filed charged misbranding in a number of ways, all of which charges have been eliminated in one way or another except that contained in paragraph IIIa, which alleged that the article was misbranded within the meaning of 21 U. S. C. A. 352 (a) in that certain representations in the labeling were false and misleading since the product, when taken as directed, will not fulfill the promises of benefit stated and implied therein.

"The special verdict of the jury, on questions framed by the court, was as follows:

1. Is the labeling of Kuriko false or misleading in that the product, when taken as directed, will not fulfill the promises of benefit, stated or implied?
Answer: Yes.
2. Does the labeling of Kuriko, including the directions thereon, provide for the continuous use of Kuriko?
Answer: No.
3. If you answer Question 2 "Yes," then answer this question. Is the continuous use of Kuriko capable of causing a dependency upon laxatives to move the bowels?
Answer:
4. Is Kuriko misbranded in that the labeling fails to bear adequate directions for use in any respect?
Answer: Yes.

"The primary issue raised before this court arises from the contention that there was no substantial evidence which would justify the submission of the case to the jury and that there should have been a directed verdict in favor of the claimant. It is also contended that the submission to the jury of question 4 was prejudicial error because there was no charge in the libel to which it was responsive. In connection with this contention, it is also asserted that the court improperly admitted the opinion testimony of a witness who was not qualified.

"Kuriko is a medicine which has long been manufactured and sold to the public. Admittedly, it is a laxative and relieves functional constipation. That is the limit, however, of its remedial qualities. In fact, we do not understand that anything further is claimed for it. Notwithstanding this, claimant in a pamphlet wrapped around each bottle of its product devoted four pages extolling benefits to be derived from its use. We think no good purpose could be served in setting forth the contents of this pamphlet. It is sufficient to state that we have studied it and we are of the view that the representations contained therein were such as to present a proper question for the jury as to whether they were misleading. It may be, as claimant insists, that there were no statements contained in the pamphlet which were literally false, but even so it does not follow that it was not misleading when considered in its entirety.

"We shall mention only a few of the statements contained in this pamphlet, from which we think a jury might have reasonably inferred that the product was represented either as a remedy or a cure for something other than constipation. On the first page, under the heading in large black type, 'What it is,' appears the following in small type, 'The family medicine of 5 generations designed for relief from functional constipation and, when these troubles are due to constipation, for relief from nervousness, indigestion, upset stomach, headaches, loss of sleep and appetite, flatulence, foul breath and coated tongue.' In other words, by this statement the reader is informed that the remedy is only a relief from the ailments mentioned when they are due to constipation. It appears there could be nothing misleading in this statement. On the same page, however, under another heading in large black type, 'What it does,' is the following statement, also in heavy type, 'Kuriko fights functional constipation.' The government contends that the buying public may infer from this statement that it is a remedy or cure for constipation rather than a mere relief. We are not greatly impressed with the government's contention in this respect but this representation, as others, was submitted to the jury and we cannot say that the jury was not justified in inferring that the statement was misleading.

"In our judgment, the more important statements in the pamphlet calculated to mislead are found on the second page, printed in large black type, 'Here's what may happen when you are constipated,' followed by five paragraphs,

entitled 'Functonal constipation,' 'Nervousness,' 'Flatulence,' 'Headaches,' and 'Common colds.' The title of each paragraph is also in heavy black type, and opposite each is a picture of a person shown to be in misery and distress. It is true that the fine print in each of these paragraphs gives the information that Kuriko will bring relief only when the ailment is caused by constipation. We are of the view, however, that this page of the pamphlet alone, considering the form of its arrangement, the ailments which are listed in large type and the limitation with reference thereto in small type, in connection with the pictures of persons evidently in misery and distress, furnishes the basis for a finding that the representations were misleading.

"A great deal of medical testimony was offered by both sides which it is argued supports the contentions of the respective parties. Again we think no useful purpose could be served in an attempt to analyze or dissect this expert testimony as it pertains to the issues in controversy. In fact, to do so would involve a weighing of the testimony, which is not our function but was that of the jury. The only contention made here which might be regarded as serious is that which arises from the submission to the jury of question 4, and its finding that Kuriko is misbranded because the labeling 'fails to bear adequate directions for use in any respect.' Concededly there was no charge in the information to which this question and answer was responsive. The only reason we find for its submission is a statement by the court that it desired an answer to the question for its own information. We are of the view that this question should not have been submitted but, even so, we are also of the view that it was not prejudicial. As this court has held, proof of any one of the claims contained in the information is sufficient. *United States* v. *Dr. Roberts Veterinary Co.*, 104 F. 2d 785, 789.

"The jury's answer to this question neither adds nor detracts from its answer to the first question, which was responsive to the charge contained in paragraph IIIa. The answer to question 1 forms the basis for a decree and this irrespective of the answer to question 4. This would still be the situation if the jury's answer to question 4 had been 'No.' There is nothing to indicate and no reason to think that the jury's answer to question 4 bore any relation to its answer to question 1. In other words, as far as we are able to discern, the jury's answer to question 1 was not dependent in any manner or to any extent upon its answer to question 4. We therefore are of the view that the submission of question 4 could have had no prejudicial effect.

"The decree is AFFIRMED."

2474. Misbranding of AlKaPectin. U. S. v. Reserve Research Co. and Herbert Williams Hoyt. Pleas of nolo contendere. Fine of $125 and costs against defendants jointly. (F. D. C. No. 24276. Sample No. 16222–K.)

INFORMATION FILED: August 13, 1948, Northern District of Ohio, against the Reserve Research Co., a corporation, Cleveland, Ohio, and Herbert Williams Hoyt, president of the corporation.

ALLEGED SHIPMENT: On or about October 30, 1947, from the State of Ohio into the State of Michigan.

PRODUCT: Analysis disclosed that the product was a white, viscous, homogenized semisolid with a slight aromatic odor and contained chiefly water, kaolin and other aluminum compounds, and a small amount of organic matter.

NATURE OF CHARGE: Misbranding, Section 502 (a), the label statement "Indicated in the treatment of Diarrhoea, Duodenitis, Colitis, Diverticulitis, Food Poisoning" was false and misleading, since the article would not be effective in the treatment of diarrhoea, duodenitis, colitis, diverticulitis, and food poisoning.

DISPOSITION: October 7, 1948. Pleas of nolo contendere having been entered, the court imposed a fine of $125 and costs against the defendants jointly.

2475. Misbranding of Vitawine. U. S. v. Interstate Laboratories, Inc. Plea of guilty. Fine of $258 and costs. (F. D. C. No. 24043. Sample Nos. 52696–H, 54133–H, 54135–H.)

INFORMATION FILED: March 10, 1948, Western District of Kentucky, against Interstate Laboratories, Inc., Louisville, Ky.

ALLEGED SHIPMENT: Between the approximate dates of September 9, 1946, and January 17, 1947, from the State of Kentucky into the State of Indiana.

PRODUCT: Analysis of samples from the 3 shipments showed the presence of 1.6, 2.01, and 2.2 grams, respectively, of iron and ammonium citrates per fluid ounce.

LABEL, IN PART: "Vitawine * * * combination of Thiamin (Vitamin B_1) 1000 U. S. P. Units, Riboflavin (Vitamin G–B_2) 100 Gammas, Niacin 10 Mg. Iron and Ammonium Citrate, Manganese Citrate, Sodium Citrate, Citric Acid and Dextrose in a palatable wine base."

NATURE OF CHARGE: Misbranding, Section 502 (a), the word "Tonic" and the statement "Iron Tonic * * * as an aid to nature in rebuilding the pep, strength and energy," which were borne on the cartons and bottles, were false and misleading. These statements represented and suggested that the article was an iron tonic which would supply therapeutic amounts of iron and would be effective for rebuilding pep, strength, and energy. The article was not an iron tonic which would supply therapeutic amounts of iron, and it would not be effective for the purposes represented.

The article was alleged also to be adulterated and misbranded under the provisions of the law applicable to foods, as reported in notices of judgment on foods.

DISPOSITION: May 26, 1948. A plea of guilty having been entered, the court imposed a fine of $258 and costs.

2476. Misbranding of phenobarbital sodium tablets. U. S. v. 68 Bottles * * *. (F. D. C. No. 25659. Sample No. 31761–K.)

LIBEL FILED: September 22, 1948, Southern District of California.

ALLEGED SHIPMENT: On or about January 16, 1948, by Cole Laboratories, from Long Island City, N. Y.

PRODUCT: 68 bottles of *phenobarbital sodium tablets* at Wilmington, Calif. Examination showed that some of the bottles labeled as containing 1,000 tablets, contained materially less than 1,000 entire tablets, together with broken and disintegrated tablets. The phenobarbital content of the unbroken tablets varied from 1.6 grains to 2.5 grains. Approximately 50% of the tablets contained either more than 2.1 grains or less than 1.8 grains of phenobarbital sodium per tablet.

LABEL, IN PART: "1000 Hypodermic Tablets Each tablet contains 2 grains (0.12 gm.) Phenobarbital Sodium * * * Distributed by Retort Pharmaceutical Co., Inc., Long Island City 1, N. Y."

NATURE OF CHARGE: Misbranding, Section 502 (a), the label statements "1000 Hypodermic Tablets" and "Each Tablet contains 2 grains * * * Phenobarbital Sodium" were false and misleading, since some of the bottles contained materially fewer whole tablets than the declared number and some tablets contained materially less and others materially more than the declared 2 grains of phenobarbital sodium.

DISPOSITION: October 19, 1948. Default decree of condemnation and destruction.

2477. Misbranding of mercuric cyanide tablets. U. S. v. 330 Bottles * * *. (F. D. C. No. 24767. Sample No. 10574–K.)

LIBEL FILED: May 10, 1948, Eastern District of New York.

ALLEGED SHIPMENT: On or about March 23 and 30 and April 5 and 7, 1948, by Veterans Administration Supply Depots, from Somerville, N. J., Montgomery, Ala., Hines, Ill., and Wilmington, Calif. (These were return shipments.)

PRODUCT: 330 100-tablet bottles of *mercuric cyanide* at Long Island City, N. Y. Examination showed that approximately ⅓ of the tablets in the bottles were capped, chipped, broken, or powdered. The average amount of mercuric cyanide in the chipped and capped tablets was 0.37 gram instead of 0.5 gram as declared.

NATURE OF CHARGE: Misbranding, Section 502 (a), the label statements "100 Tablets Mercuric Cyanide Each tablet contains 0.5 Gm (7½ grs.) Mercuric Cyanide" were false and misleading, since there were less than 100 whole tablets in each bottle and some of the tablets, namely, those which were chipped and capped, contained less than 0.5 gram of mercuric cyanide.

DISPOSITION: July 28, 1948. Default decree of condemnation and destruction.

2478. Misbranding of natural estrogens. U. S. v. 175 Vials * * *. (F. D. C. No. 23987. Sample No. 14205–K.)

LIBEL FILED: December 10, 1947, Northern District of Illinois.

ALLEGED SHIPMENT: On or about June 27, 1947, by the Harrower Laboratory, from Glendale, Calif.

PRODUCT: 175 30-cc. vials of *natural estrogens* at Chicago, Ill.

LABEL, IN PART: "Plestrin in Oil Brand of Natural Estrogens in Oil."

NATURE OF CHARGE: Misbranding, Section 502 (a), the label statement "A concentrate of natural estrogens derived from gravid mares' urine, equivalent in terms of estrone to 10,000 I. U. per cc. (1.0 mg. crystalline estrone)" was false and misleading, since the article did not contain per cubic centimeter a concentrate of natural estrogens derived from gravid mares' urine equivalent in terms of estrone to 10,000 International Estrone Units or 1.0 milligram of crystalline estrone, but owed its apparent potency of approximately 9000 International Estrone Units in whole or in part to estrogens other than a concentrate of natural estrogens as they occur in and are extracted from the urine of gravid mares.

DISPOSITION: February 25, 1948. Default decree of condemnation and destruction.

2479. Misbranding of Estradocreme, Nephrocrine, Androcrine, Orchicrine, and Io-Plexa-Dine. U. S. v. 14 Jars, etc. (F. D. C. No. 21321. Sample Nos. 48218–H to 48220–H, incl., 48222–H, 48226–H.)

LIBEL FILED: October 31, 1946, District of Colorado; amended libel filed March 23, 1948, Northern District of California.

ALLEGED SHIPMENT: On or about May 31 and September 12, 23, 25, and 26, 1946, by the Woodard Laboratories, from Los Angeles, Calif.

PRODUCT: 14 jars, each containing 28½ grams, of *Estradocreme*, 11 cartons, each containing 90 tablets, of *Nephrocrine*, 5 bottles, each containing 30 cc., of *Androcrine*, 8 cartons, each containing 90 tablets, of *Orchicrine*, and 5 1-ounce bottles of *Io-Plexa-Dine*, at Denver, Colo., together with a number of booklets shipped in June 1946 entitled "Woodard Manual Formulae and Related Information."

Analysis disclosed that the *Estradocreme* was a perfumed cream containing an estrogen; that the *Nephrocrine* contained glandular material; that the *Androcrine* contained a ketosteroid such as an androgen, alcohol 78 percent, and a fatty substance; that the *Orchicrine* contained kelp, glandular material, and a manganese salt; and that the *Io-Plexa-Dine* contained glycerin, iodine, and a small proportion of a phenol.

NATURE OF CHARGE: *Estradocreme.* Misbranding, Section 502 (a), certain statements in the booklets were false and misleading, since they represented and suggested that the article when used as directed was effective to stimulate breast development and to increase the size of breasts. The article when used as directed was not effective for such purposes.

Nephrocrine. Misbranding, Section 502 (a), the designation "Nephrocrine" was misleading, since it suggested and implied that the article contained therapeutically useful constituents derived from kidney and one or more of the endocrine glands, whereas such was not the case; and the misleading impression of such designation was not corrected or nullified by the statement elsewhere upon the label "There are no scientific data available to indicate that the desiccated glandular substances in this product are physiologically or therapeutically active." Further misbranding, Section 502 (a), certain statements in the booklets were false and misleading, since they represented and suggested that the article was effective for the control of albuminuria and decreased permeability of the kidney glomerulus associated with nephritis and nephrosclerosis. The article was not effective for such purposes.

Androcrine. Misbranding, Section 502 (a), the designation of the article "Androcrine Inunction" and the statement on the labels "For the inunctious administration of androgenic substance when indicated" were misleading, since they suggested and implied that the article supplied when administered in accordance with the directions in the labeling, namely, "Average Dose: Apply fifteen drops to the inner aspects of each thigh and the lower abdomen daily. Massage gently until liquid disappears," a therapeutically significant amount

of androgen, a substance elaborated by an endocrine gland, whereas the article when administered in accordance with the directions would not supply a therapeutically significant amount of androgen. Further misbranding, Section 502 (a), certain statements in the booklets were false and misleading, since they represented and suggested that the article was effective to modify or influence the male climacteric and was effective for conditions associated with androgenic deficiencies, whereas it was not effective for such purposes; and, Section 502 (e) (2), the article was fabricated from two or more ingredients and its label failed to bear a statement of the proportion of any alcohol contained therein, since the statement "Alcohol 95%" was not an accurate statement of the proportion of alcohol contained in the article.

Orchicrine. Misbranding, Section 502 (a), the designation "Orchicrine" was misleading, since it suggested and implied that the article contained therapeutically useful constituents derived from the orchic gland, an endocrine gland, whereas it did not contain such constituents; and the misleading impression of such designation was not corrected or nullified by the label statement "There are no scientific data available to indicate that the desiccated glandular substances contained in this product are physiologically or therapeutically active." Further misbranding, Section 502 (a), certain statements in the booklets were false and misleading, since they represented and suggested that the article was effective as supportive to androgen therapy in hypogonadism and in the male climacteric, whereas the article was not effective for such purposes.

Io-Plexa-Dine. Misbranding, Section 502 (a), the following statements in the booklets were false and misleading, since the article would exhibit effects similar to those of other iodine-containing substances, and it would not accomplish the therapeutic results stated and implied: "Io-Plexa-Dine can be administrated for a long time in comparatively large doses without displaying the usual physiological manifestations of iodism * * * Io-Plexa-Dine does not exhibit the usual toxic effects of iodine when taken internally * * * A complete bodily saturation is thereby possible without any harmful effects * * * Indications for use of Io-Plexa-Dine include * * * thyrotoxicosis (Grave's Disease or hyperthyroidism). A number of cases of arthritis have also been reported as successfully controlled with Io-Plexa-Dine and some physicians claim complete cure for patients with advanced arthritic disease wherein large growths of osseous tissue and protuberances of the normal bone structure have been extensive. These areas of abnormal ossification have been completely eliminated. Some physicians have reported actual withdrawal of calcium from the arteries in arteriosclerosis. Its use is also indicated in cases of asthma and bronchitis. In stomach and intestinal conditions, Io-Plexa-Dine has been reported as being successfully used in the management of peptic and duodenal ulcers, amebic infection of the gut and in cases of extensive infection of the colon (colitis). As a topical application Io-Plexa-Dine is valuable as an antiseptic in otitis media (middle ear disease), and as a tonsil and throat spray for tonsilitis, pharyngitis and laryngitis * * * As a dietary supplement for * * * thyrotoxicosis (Grave's Disease or hyperthyroidism). Topically in otitis media; as a throat spray for tonsillitis, pharyngitis, laryngitis * * * Trichomonas vaginalis. Experimental only—arthritis hypertrophic or osteo; arteriosclerosis * * * systemic infections; pathologies attendant with fibrous exudaton; tertiary syphilis; inoperable lymphadenitis; actinomycosis; pleurisy; pericarditis; chronic inflammatory conditions accompanied by a formation of fibroid connecting tissue, such as interstitial nephritis; locomotor ataxia; chronic rheumatism; lead poisoning or mercurial cachexia. Dosage: Chronic Pathologies; Begin with five drops after each meal and increase one drop daily until thirty drops are taken three times daily. * * * Thyrotoxicosis: Start with five drops and gradually increase to fifteen drops three times daily."

DISPOSITION: Woodard Laboratories, Inc., appeared as claimant and filed a motion for removal of the case for trial in the Northern District of California, which motion was granted on December 19, 1946. The claimant withdrew its claim on June 4, 1948, and on June 18, 1948, a decree of condemnation and destruction was entered.

2480. Misbranding of Prostall. U. S. v. 79 Bottles, etc. (F. D. C. No. 23649. Sample Nos. 29679–H, 62855–H.)

LIBEL FILED: September 9, 1947, Northern District of California.

ALLEGED SHIPMENT: On or about June 25 and August 8, 1947, by Douglas Laboratories, from Boston, Mass.

PRODUCT: 79 100-capsule bottles of *Prostall* at San Francisco, Calif., together with 120 leaflets entitled "The Story of Prostall." Analysis indicated that the product consisted essentially of glutamic acid.

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements on the label of the article and in the leaflets were false and misleading, since they represented and suggested that the article was effective in the relief of pain and prostate hypertrophy, whereas the article would not be effective for such purposes.

DISPOSITION: February 27, 1948. Default decree of condemnation and destruction.

2481. Misbranding of Gramer's Sulgly-Minol. U. S. v. 100 Bottles, etc. (F. D. C. No. 24921. Sample No. 24582–K.)

LIBEL FILED: June 30, 1948, Western District of Wisconsin.

ALLEGED SHIPMENT: The product was shipped on or about April 16, 1948, and a number of circulars were shipped on or about May 15, 1948, from Minneapolis, Minn., by Walter W. Gramer.

PRODUCT: 100 4-ounce bottles of *Gramer's Sulgly-Minol* at Eau Claire, Wis., together with 100 circulars entitled "Arthritis Its Grip Broken" and 100 circulars entitled "A Light Should Not Be Hidden." Analysis indicated that the product consisted essentially of a lime and sulfur solution with a small amount of glycerin.

LABEL, IN PART: "Gramer's Sulgly-Minol."

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements on the label of the article and in the circulars were false and misleading, since they represented and suggested that the article was effective in the relief and treatment of arthritis, muscular pains, rheumatism, stiffness and soreness in the legs and knees, athlete's foot, boils, and acne, whereas the article would not be effective for the purposes represented.

DISPOSITION: August 9, 1948. Default decree of forfeiture and destruction.

2482. Misbranding of Paracelsus. U. S. v. 108 Cans, etc. (F. D. C. No. 23657. Sample Nos. 69018–H, 70034–H.)

LIBEL FILED: September 25, 1947, Northern District of Illinois.

ALLEGED SHIPMENT: By the American Biochemical Corp., from Cleveland, Ohio. The product was shipped on or about June 10 and August 6, 1947, and a number of printed folders were shipped on or about March 31 and August 4, 1947.

PRODUCT: 108 1-pound, 5-ounce cans, of *Paracelsus* at Chicago, Ill., together with a number of printed folders entitled "Paracelsus Its Origin What It Is Comments." Analysis disclosed that three-fourths of a level teaspoonful of the product contained 58 milligrams of calcium, 127 milligrams of phosphorus, 0.54 milligram of iron, and 0.47 milligram of iodine. These quantities were about one-half the amounts of calcium, phosphorus, and iron, and more than five times the amount of iodine, represented by the labeling as present in the product.

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements on the label of the article were false and misleading, since they represented and suggested that the article if taken as directed would supply the given percentages of calcium, phosphorus, iron, and iodine stated, whereas the article would supply materially less calcium, phosphorus, and iron, and materially more iodine than stated.

Further misbranding, Section 502 (a), certain statements in the folders were false and misleading, since they represented and suggested that the article when consumed as directed would supply the mineral requirements of a healthy 150-pound man; that it would contribute substantially to the health of the consumer; that its use would maintain the alkali reserve and prevent trouble developing from an acid condition; that its use would insure

against insufficiency of mineral salts and an attendant rise in acidity; that it would supply minerals deficient in food because of loss in cooking and in fruits and vegetables grown upon depleted soil; that its use would produce results comparable to those obtained at mineral springs; that its use would prevent or remedy illness caused by mineral deficiency; that it would be effective in the building of bones, teeth, and other hard parts of the body; that by reason of its iron and copper content it would enable the blood to carry oxygen; that by acting as a catalyst it would help digestion; that it would supply the minerals necessary for cell-building purposes; that when taken as directed it would supply the following percentages of daily requirements for persons: "Calcium 15% for those over one year of age, 7.5% for pregnant or lactating women Phosphorus 30% for those over one year of age, 15% for pregnant or lactating women Iron 20% for those over one year of age, 15% for those over six years of age, 10% for pregnant or lactating women"; that it was of nutritional value by reason of its content of lithium, manganese, magnesium, sulfur, chlorine, sodium, potassium, silica, and copper; that it would adequately supplement the diet with respect to certain minerals of which deficiencies often exist; that mineral supplements to the normal diet are essential for perfect health; that the system can make use of minerals without vitamins, but cannot utilize vitamins without minerals; that the ingredients of the article were in a mutually balanced ratio; and that the article had the approval of physicians having a knowledge of biochemistry. The above-mentioned representations and suggestions were untrue in fact and created misleading impressions.

The article was alleged also to be misbranded under the provisions of the law applicable to foods, as reported in notices of judgment on foods.

DISPOSITION: January 29, 1948. Default decree of condemnation and destruction.

2483. Misbranding of Burtone. U. S. v. 36 Cartons * * *. (F. D. C. No. 24341. Sample No. 2457–K.)

LIBEL FILED: February 9, 1948, Southern District of Ohio.

ALLEGED SHIPMENT: On or about January 6, 1948, by Drug Profits, Inc., from Ravenswood, W. Va.

PRODUCT: 36 cartons, each containing 12 boxes, of *Burtone* at Ironton, Ohio. Examination showed that the product consisted essentially of emodin bearing drugs, phenolphthalein, extract of bile, capsicum, and oil of peppermint.

LABEL, IN PART: "Burtone Lower Bowel and General Laxative 30 tablets."

NATURE OF CHARGE: Misbranding, Section 502 (a), the following label statements were false and misleading, since the article was a laxative and a laxative is not effective in bringing about lower bowel health; is not effective in the treatment of sickness resulting from constipation; and is not effective for the other diseases, symptoms, and conditions represented and suggested to be a result of constipation: (Display carton) "The Lower Bowel Health Plan Burtone for Constipation Sickness and Headache, stomach gas, indigestion, biliousness, backache, rheumatic pains, etc. caused by the ailment" and (circular in box) "Constipation Sickness This Refers Directly To Headaches—Bilious Spells — Stomach Gases — Indigestions — Heartburns — Backaches — Loss of Energy and a Weak, Tired Body When Such Conditions Are Due to or Symptomatic of Prolonged Constipation. Constipation Sickness: Meaning Headaches, Bilious Spells, Stomach Gases, Indigestions, Heartburns, Backaches, Loss of Energy, A Tired, Achy Body when due to or symptomatic of lower bowel constipation and responsive to the right use of an effective laxative * * * It is here that toxic poisons form and are carried back on gas waves into the small intestinal tract where they become the cause of these defined inorganic ailments that soon cause the distresses mentioned."

Further misbranding, Section 502 (a), the directions for the use of the article and the advice against too frequent use were misleading, in that they were ambiguous since the user was furnished with directions calling for continued administration of the article and was then admonished against taking the article in the following words: "When the need continues after the first dose, three additional doses are permissible, after eight hours' rest period, as follows: two regular and one reduced to one-half the regular; with eight hour rest periods between each of the three doses. Then a rest period of three

days when as much of the directed use as deemed necessary may be repeated * * * Not forgetting that too frequent use of this or any laxative may result in a dependence on them."

DISPOSITION: March 29, 1948. Default decree of condemnation and destruction.

2484. Misbranding of Hemcaps. U. S. v. 59 Bottles * * *. (F. D. C. No. 24719. Sample No. 6442–K.)

LIBEL FILED: April 12, 1948, Western District of New York.

ALLEGED SHIPMENT: On or about March 17, 1948, by the Marlo Products Co., from Cleveland, Ohio.

PRODUCT: 59 50-capsule bottles of *Hemcaps* at Rochester, N. Y., together with 480 leaflets entitled "Hemcaps For Relief of Piles."

LABEL, IN PART: "Hemcaps * * * Active Ingredients: Yellow Dock, Horse Chestnut, Witch Hazel and Stone Root."

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements on the label of the article, on the display carton, and in the leaflets shipped with the article were false and misleading, since they represented and suggested that the article was effective in relieving and treating hemorrhoids, whereas it was not effective for such purposes.

DISPOSITION: May 12, 1948. Default decree of condemnation and destruction.

2485. Misbranding of Cravex. U. S. v. 83 Cartons * * *. (F. D. C. No. 24613. Sample No. 18535–K.)

LIBEL FILED: April 23, 1948, Southern District of Ohio.

ALLEGED SHIPMENT: On or about March 28, August 5, September 26, and November 24, 1947, by the Plant Products Co., Inc., from Burbank, Calif.

PRODUCT: 83 cartons of *Cravex* at Dayton, Ohio. Examination showed that the product consisted essentially of calcium and magnesium phosphates and glycerophosphates, caffeine, and milk sugar.

NATURE OF CHARGE: Misbranding, Section 502 (a), the following statements in the labeling of the article were false and misleading, since the article was not a treatment for the causes and effects of over-indulgence in liquor: (Carton) "Cravex" and (circular within carton) "It has been shown that alcohol chiefly affects the nervous system, which causes nervous irritability and frequently results in malnutrition. Cravex is a nerve tonic which contains several substances which are helpful in the treatment of both the causes and effects of over-indulgence."

DISPOSITION: June 18, 1948. Default decree of condemnation and destruction.

2486. Misbranding of Denver Mud. U. S. v. 6 Cases * * *. (F. D. C. Nos. 24744, 24745. Sample Nos. 28497–K, 28498–K.)

LIBELS FILED: April 29, 1948, Western District of Texas.

ALLEGED SHIPMENT: On or about April 6, 1948, by Demco, Inc., from Denver, Colo.

PRODUCT: 4 cases, each containing 72 4½-ounce jars, and 2 cases, each containing 36 8-ounce jars, of *Denver Mud* at El Paso, Tex., together with an accompanying circular entitled "Medicated Denver Mud." Examination showed that the product consisted essentially of clay, mixed with boric acid, glycerin, resorcinol, and essential oils.

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements on the label of the article and in the circular were false and misleading, since they represented and suggested that the article constituted an adequate treatment for boils, sprains, congestion, inflammation, chest colds, skin irritations, chilblains, frostbite, pulmonary affections, pneumonia, and pimples. The article was not an adequate treatment for such diseases, symptoms, and conditions.

DISPOSITION: July 12, 1948. Default decrees of condemnation and destruction.

2487. Misbranding of Marvel Bath and Marvel Cream. U. S. v. Aaron N. Sawyer, also known as A. Neil Sawyer, (American Vita Products Co.). Plea of guilty. Fine, $500. (F. D. C. No. 24258. Sample Nos. 91149–H, 91150–H.)

INFORMATION FILED: June 10, 1948, Southern District of New York, against Aaron N. Sawyer, also known as A. Neil Sawyer, doing business as the American Vita Products Co., New York, N. Y.

ALLEGED SHIPMENT: On or about March 21, 1947, from the State of New York into the State of New Jersey.

NATURE OF CHARGE: Misbranding, Section 502 (a), the statement "Relax While Reducing" appearing on the label of the *Marvel Bath* was false and misleading, since it represented and suggested that the *Marvel Bath* and the *Marvel Cream* would be efficacious to cause the user to lose weight, whereas the products would not be efficacious to cause the user to lose weight.

DISPOSITION: September 3, 1948. A plea of guilty having been entered, the court imposed a fine of $500.

2488. Misbranding of Holly Bath and Holly Cream. U. S. v. Hollywood Vita Products Co. Plea of nolo contendere. Fine, $250. (F. D. C. No. 24273. Sample No. 36317–K.)

INFORMATION FILED: July 21, 1948, Southern District of California, against the Hollywood Vita Products Co., a partnership, Hollywood, Calif.

ALLEGED SHIPMENT: On or about October 13, 1947, from the State of California into the State of Washington.

PRODUCT: Analysis of the *Holly Bath* showed that it consisted essentially of epsom salt, sulfur, and a small proportion of pine oil, and that the *Holly Cream* consisted essentially of epsom salt, soap, water and perfume.

NATURE OF CHARGE: Misbranding, Section 502 (a), the statement "Relax While Reducing," displayed upon the package containing the *Holly Bath*, was false and misleading. This statement represented and suggested that the *Holly Bath* and *Holly Cream* would be efficacious to cause the user to lose weight, whereas they would not be efficacious for such purpose.

DISPOSITION: On August 19, 1948, a motion to dismiss was filed on behalf of the defendant on the ground that the information did not state facts sufficient to show a violation of the statute. After consideration of the briefs of the parties, the court, on August 30, 1948, denied the motion. A plea of nolo contendere was thereupon entered, and on September 13, 1948, the court imposed a fine of $250.

2489. Misbranding of reducing and health bath and cream. U. S. v. Margaret Sevier (Dr. Ferenz Michel's Laboratories). Plea of nolo contendere. Fine, $50. (F. D. C. No. 24246. Sample Nos. 66338–H, 66339–H.)

INFORMATION FILED: April 7, 1948, Eastern District of Pennsylvania, against Margaret Sevier, trading as Dr. Ferenz Michel's Laboratories, Philadelphia, Pa.

ALLEGED SHIPMENT: On or about May 29, 1947, from the State of Pennsylvania into the State of New Jersey.

PRODUCT: Analysis disclosed that the bath preparation consisted essentially of epsom salt, with a small amount of a volatile oil resembling pine oil, and that the cream preparation resembled vanishing cream and possessed an odor of methyl salicylate.

LABEL, IN PART: "Dr. Ferenz Michel's Reducing & Health Bath [or "Cream"]."

NATURE OF CHARGE: Misbranding, Section 502 (a), the statements "Reducing & Health Bath A Reducing Aid * * * Reducing Bath * * * Excellent Aid in the relief of Rheumatic and Arthritis Pains," borne on the label of the bath preparation, and the statement "An Aid For Reducing," borne on the label of the cream preparation, were false and misleading. The bath preparation would not be efficacious as a reducing aid and as a health aid, and it would not be efficacious to furnish relief from rheumatic and arthritic pains; and the cream preparation would not be efficacious as a reducing aid.

DISPOSITION: June 7, 1948. A plea of nolo contendere having been entered, the court imposed a fine of $50.

2490. Misbranding of Slenda-Bath. U. S. v. 70 Cartons, etc. (F. D. C. No. 24721. Sample No. 15158–K.)

LIBEL FILED: April 12, 1948, Western District of Michigan.

ALLEGED SHIPMENT: On or about March 17, 1948, by Richard Faxon Co., from Chicago, Ill.

PRODUCT: 70 cartons, each containing 10 herb packets, of *Slenda-Bath* at Grand Rapids, Mich., together with one plastic cape and a number of circulars entitled "Reduce While You Bathe," which were shipped with the product.

LABEL, IN PART: (Carton) "Slenda-Bath Reducing Plan Contents Active Ingredients: Herbs—Wood Guiaic, Water Pepper, Arbor Vitae, Sassafras Bark of the root; Wetting Agents—Sodium Laryl Sulponate, Sodium Alkyl Sulponate, Oil of Sassafras, Certified Coloring; Inert Ingredients—Water Softening Compounds."

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements in the labeling of the article which represented and suggested that the article would be effective in bringing about a reduction in body weight were false and misleading, since the article would not be effective for such purpose.

DISPOSITION: July 29, 1948. Default decree of condemnation and destruction.

2491. Misbranding of Mentos. U. S. v. 40 Cases * * *. (F. D. C. No. 24742. Sample No. 10498–K.)

LIBEL FILED: April 29, 1948, Southern District of New York.

ALLEGED SHIPMENT: On or about January 14, 1948, by Mentos Products, from Philadelphia, Pa.

PRODUCT: 40 cases, each containing 12 ½-pint bottles, of *Mentos* at New York, N. Y. Examination showed that the product consisted essentially of sulfur, ammonia, borates, carbonates, and water.

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements in a circular entitled "Mentos Medicine," which was attached to each bottle of the article, were false and misleading, since they represented and suggested that the article was effective in the treatment of scalp and skin diseases, severe cases of dandruff, eczema, psoriasis, ringworm, excess falling hair, and dry hair, and that the article would relieve inflammation of the glands and acne, whereas it would not be effective for such purposes.

DISPOSITION: May 26, 1948. Default decree of condemnation and destruction.

2492. Misbranding of Hairmore. U. S. v. 45 Bottles, etc. (F. D. C. No. 24723. Sample Nos. 4663–K, 4671–K.)

LIBEL FILED: April 16, 1948, District of Massachusetts.

ALLEGED SHIPMENT: On or about November 6 and December 12, 1947, and March 15, 1948, by Gilmore-Burke, Inc., from Seattle, Wash.

PRODUCT: 45 2-ounce bottles and 44 4-ounce bottles of *Hairmore* at Boston, Mass., together with a number of circulars entitled "Good looking hair is a Real Asset" and a number of newspaper reprints entitled "Are You Bald? Priest Finds Hair Restorer." Examination disclosed that the product was a two-layer liquid, the upper layer consisting essentially of a saponifiable oil, and the lower layer consisting essentially of glycerin, boric acid, resorcinol, and tincture of nux vomica.

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements in the labeling of the article were false and misleading, since they represented and suggested that the article was effective in promoting the growth of hair and overcoming scalp disorders, whereas the article was not effective for such purposes.

DISPOSITION: August 31, 1948. Default decree of condemnation and destruction.

2493. Misbranding of Spectro-Chrome. U. S. v. 1 Device * * *. (F. D. C. No. 16829. Sample No. 4174–H.)

LIBEL FILED: July 19, 1945, Eastern District of Michigan.

ALLEGED SHIPMENT: On or about June 29, 1945 by the Dinshah Spectro-Chrome Institute, from Newfield, N. J.

PRODUCT: 1 *Spectro-Chrome* device at Detroit, Mich. The construction and appearance of the device was essentially the same as that of the device involved in notices of judgment on drugs and devices, No. 2098.

The device was accompanied by the following pieces of printed and graphic matter: "Spectro-Chrome Home Guide," "Favorscope for 1945," "Rational Food of Man," "Key to Radiant Health," "Request for Enrollment as Benefit Student," "Auxiliary Benefit Notice—Make Your Own Independent Income as Our Introducer," "Spectro-Chrome General Advice Chart for the Service of Mankind—Free Guidance Request," "Certificate of Benefit Studentship," "Spectro-Chrome—December 1941—Scarlet," and "Spectro-Chrome—March 1945—Yellow."

NATURE OF CHARGE: Misbranding, Section 502 (a), the labeling of the device bore false and misleading curative and therapeutic claims in substantially the same respect as the device involved in notices of judgment on drugs and devices, No. 2098.

DISPOSITION: September 25, 1945. Default decree of condemnation and destruction. The device was ordered delivered to the Food and Drug Administration, to be used for experimental purposes and in a pending criminal action against the shipper.

2494. Misbranding of Roll-A-Ray. U. S. v. 53 Devices * * *. (F. D. C. No. 24587. Sample No. 20834–K.)

LIBEL FILED: On or about April 13, 1948, Western District of Missouri.

ALLEGED SHIPMENT: On or about October 10, 1947, by the O. A. Sutton Corp., from Wichita, Kans.

PRODUCT: 53 *Roll-A-Ray* devices at Kansas City, Mo. Examination showed that the device, resembling an electric iron in shape and size, consisted of a brown plastic molded case with handle attached. The case enclosed a light bulb and two rubber rollers placed at either end of the bottom part of the case. The rollers contacted the body for massaging purposes, and the light bulb furnished heat. A plastic grid was fitted over the bulb to protect the body from contact with the lamp.

LABEL, IN PART: "Roll-A-Ray Heat Massage With Infra Red."

NATURE OF CHARGE: Misbranding, Section 502 (a), the following label statements were false and misleading, since heat and massage are not adequate treatments for such purposes: "For Home Reducing and an Aid in the Relief of Discomforts Arising from Rheumatism, Lumbago, Muscular Aches, Physical Pains * * * for Health and Beauty * * * to remove fatty tissues. Many varied ailments respond to application of heat and massage * * * for loosening muscles and assisting in driving fatty tissues away."

DISPOSITION: September 28, 1948. Default decree of destruction.

2495. Misbranding of Beauty Roll. U. S. v. 24 Devices * * *. (F. D. C. No. 24704. Sample No. 2028–K.)

LIBEL FILED: April 1, 1948, District of Columbia.

PRODUCT: 24 *Beauty Roll* devices which were held for sale in interstate commerce in the District of Columbia by Vita Food Stores, together with a number of display placards and leaflets entitled "Reduce with the Beauty Roll * * * Dandd, Inc., New York."

Examination showed that the device consisted of three rubber-like balls mounted so as to rotate on an axis between two wooden handles.

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements, and designs consisting of pictures of the device and of a slender woman using the device, appearing on the label, were false and misleading. These statements and designs represented and suggested that the device when used as directed was effective to reduce excess body weight, whereas the device was not effective for such purpose.

DISPOSITION: August 4, 1948. Default decree of condemnation and destruction.

DRUGS FOR VETERINARY USE

2496. Misbranding of Guaialyptol and Guiasol. U. S. v. 22 Bottles of Guaialyptol, etc. (F. D. C. No. 24127. Sample Nos. 25039–K to 25042–K, incl.)

LIBEL FILED: November 29, 1947, District of Minnesota.

ALLEGED SHIPMENT: On or about October 29 and November 7, 1947, by Fort Dodge Laboratories, Inc., from Fort Dodge, Iowa. The circulars were shipped on or about October 19, 1947.

PRODUCT: 22 1-gallon bottles of *Guaialyptol* and 6 1-gallon bottles of *Guiasol* and 60 circulars entitled "in swine 'flu' * * * Guaialyptol * * * Guiasol" at Minneapolis, Minn. Examination showed that the *Guaialyptol* consisted essentially of guaiacol liquid, eucalyptus oil, camphor oil, cresol, and saponaceous oils. The *Guiasol* consisted essentially of potassium guaiacol sulfonate, potassium arsenite, and ammonium chloride 8%, in an aromatic glycerinated base.

NATURE OF CHARGE: *Guaialyptol.* Misbranding, Section 502 (a), the statements "in swine 'flu' * * * Indicated in all pulmonary troubles of animals" and the design of a sick hog which appeared in the circulars entitled "in swine 'flu' * * * Guaialyptol * * * Guiasol" were false and misleading, since the product would not be an effective treatment for swine influenza and all pulmonary troubles of animals.

Guiasol. Misbranding, Section 502 (a), the statement "in swine 'flu' * * * Especially valuable in swine influenza of porcine pneumonia, coryza and roup of fowls, shipping fever and kindred troubles of horses, cattle and sheep," appearing in the circulars entitled "in swine 'flu' * * * Guaialyptol * * * Guiasol," were false and misleading since the product would not be an effective treatment for swine influenza and pneumonia, coryza and roup of fowls, shipping fever and kindred troubles of horses, cattle, and sheep.

DISPOSITION: February 28, 1948. Fort Dodge Laboratories, Inc., claimant, having consented to the entry of a decree, judgment of condemnation was entered and the product was ordered released under bond to be relabeled under the supervision of the Food and Drug Administration.

2497. Misbranding of Poultry Prep. U. S. v. 17 Bottles, etc. (F. D. C. No. 24902. Sample No. 24583–K.)

LIBEL FILED: June 30, 1948, Western District of Wisconsin.

ALLEGED SHIPMENT: On or about May 10, 1948, by the Wonder Chemical Co., from Minneapolis, Minn.

PRODUCT: 17 1-quart bottles, 7 ½-gallon bottles, and 8 1-gallon bottles of *Poultry Prep.* at Durand, Wis.

LABEL, IN PART: "Poultry Prep. Astringent and Acidifying Preparation for Poultry Active Ingredients: Sodium Sulpho-carbolate, Sulphuric Acid, Iron Sulphate, Manganese Sulphate. Inert Ingredients: Artificial Oil of Sassafras .3%, Epsom Salts, 4.3%., Water 83%. Total Drugs 17%."

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements on the label of the article were false and misleading, since they represented and suggested that the article when used as directed was of value in the prevention and treatment of disease conditions of chickens and turkeys, whereas the article when used as directed was not of value for such purposes.

DISPOSITION: August 9, 1948. Default decree of forfeiture and destruction.

2498. Misbranding of Sep-Tone. U. S. v. 12 Bottles, etc. (F. D. C. No. 24918. Sample Nos. 45601–K to 45603–K, incl.)

LIBEL FILED: June 28, 1948, Eastern District of Illinois.

ALLEGED SHIPMENT: On or about April 5 and May 10 and 28, 1948, by Dolan Laboratories, from St. Louis, Mo.

PRODUCT: 12 1-gallon bottles, 16 1-quart bottles, and 24 ½-gallon bottles of *Sep-Tone* at Mascoutah, Ill.

LABEL, IN PART: "Sep-Tone for Poultry Drinking Water Contains: Potassium Guaiacol-Sulfonate, Ammonium Chloride, Iodine, Potassium Iodide, Sodium Sulfocarbolate, Zinc Sulfocarbolate, Copper Sulfocarbolate, Potassium Dichromate and Water."

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements on the label of the article were false and misleading, since they represented and suggested that the article was of value as a tonic for septic conditions and that when used as directed it was of value in the prevention and treatment of disease conditions of poultry and rabbits, whereas the article was not effective for the purposes represented.

DISPOSITION: August 10, 1948. Default decree of condemnation and destruction.

DRUG ACTIONABLE BECAUSE OF OMMISSION OF, OR UNSATISFACTORY, INGREDIENTS STATEMENTS*

2499. Misbranding of E–E Double Ease Powders. U. S. v. 897 Packages * * *. (F. D. C. No. 24853. Sample No. 347–K.)

LIBEL FILED: June 1, 1948, Western District of North Carolina.

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*See also Nos. 2453, 2457, 2479.

ALLEGED SHIPMENT: On or about April 15, 1948, by the E-E Medicine Co., from Greenville, S. C.

PRODUCT: 897 packages of *E-E Double Ease Powders* at Hendersonville, N. C. Examination showed excessive variations in the dose supplied by the individual powders. 24 powders examined were found to supply from 2.11 to 3.57 grains of acetanilid and from 6.92 to 11.69 grains of potassium bromide.

LABEL, IN PART: "E-E Double Ease Powders * * * Each powder contains 2½ Grains Acetanilid and 7½ Grains Potassium Bromide * * * This envelope contains two powders."

NATURE OF CHARGE: Misbranding, Section 502 (e) (2), the article was fabricated from two or more ingredients and its label failed to bear a statement of the quantity of acetanilid and potassium bromides contained therein, since the label declarations of such ingredients were incorrect.

DISPOSITION: July 9, 1948. Default decree of condemnation and destruction.

DRUG ACTIONABLE BECAUSE OF FAILURE TO COMPLY WITH PACKAGING REQUIREMENTS OF AN OFFICIAL COMPENDIUM

2500. Misbranding of gauze pads. U. S. v. 3 Cartons, etc. (F. D. C. No. 23510. Sample Nos. 87165–H, 87166–H.)

LIBEL FILED: July 18, 1947, District of Maine.

ALLEGED SHIPMENT: On or about May 21, 1947, by the Handy Pad Supply Co., from Worcester, Mass.

PRODUCT: 3 cartons, each containing 72 packages, and 2 cartons, each containing 100 packages, of *gauze pads* at Portland, Maine.

LABEL, IN PART: "100 Ideal Dispenser Type Gauze Pads * * * Sterilized," or "Frye's Gauze Pads * * * Sterilized."

NATURE OF CHARGE: Misbranding, Section 502 (g), the article purported to be "Sterile Absorbent Gauze," a drug the name of which is recognized in the United States Pharmacopoeia, an official compendium, and it was not packaged as prescribed therein, since the pads were not packaged individually. The compendium provides that each sterile absorbent gauze unit shall be so packaged individually that the sterility of the unit is maintained until the package is opened for use.

DISPOSITION: September 8, 1947. The Handy Pad Supply Co., claimant, having admitted the allegations of the libel, judgment of condemnation was entered and the product was ordered released under bond for repackaging and relabeling in accordance with the law, under the supervision of the Food and Drug Administration.

INDEX TO NOTICES OF JUDGMENT D. D. N. J. NOS. 2451 TO 2500

PRODUCTS

[1] (2453, 2460) Permanent injunction issued.
[2] (2461) Seizure contested.

SHIPPERS, MANUFACTURERS, AND DISTRIBUTORS

[1] (2453, 2460) Permanent injunction issued.
[2] (2461) Seizure contested.
[3] (2473) Seizure contested. Contains opinions of district court and circuit court.

[1] (2453, 2460) Permanent injunction issued.
[3] (2473) Seizure contested. Contains opinions of district court and circuit court.

U. S. GOVERNMENT PRINTING OFFICE: 1949

D. D. N. J., F. D. C. 2501–2550

Issued August 1949

FEDERAL SECURITY AGENCY

FOOD AND DRUG ADMINISTRATION

NOTICES OF JUDGMENT UNDER THE FEDERAL FOOD, DRUG, AND COSMETIC ACT

[Given pursuant to section 705 of the Food, Drug, and Cosmetic Act]

2501–2550

DRUGS AND DEVICES

The cases reported herewith were instituted in the United States district courts by the United States attorneys acting upon reports submitted by direction of the Federal Security Administrator.

J. DONALD KINGSLEY, *Acting Administrator, Federal Security Agency.*

WASHINGTON, D. C., *February 28, 1949.*

CONTENTS*

DRUGS AND DEVICES ACTIONABLE BECAUSE OF FAILURE TO BEAR ADEQUATE DIRECTIONS OR WARNING STATEMENTS

2501. Misbranding of seconal sodium capsules and amytal tablets. U. S. v. Harry Skepner (Harry Skepner Prescription Pharmacy). Plea of nolo contendere. Defendant fined $2,000 and sentenced to 1 year's imprisonment. Prison sentence suspended for period of 3 years and defendant placed on probation. (F. D. C. No. 24261. Sample Nos. 44830–H, 44831–H.)

INFORMATION FILED: April 27, 1948, Southern District of California, against Harry Skepner, trading as Harry Skepner Prescription Pharmacy at Hollywood, Calif.

ALLEGED SHIPMENT: On or about May 7, 1947, from the State of California into the State of Arizona.

LABEL, IN PART: "Harry Skepner Rx Prescription Pharmacist Rx Sick Room Supplies 6255 Hollywood Blvd. Hollywood, Calif."

*For presence of a habit-forming narcotic without warning statement, see No. 2501; omission of, or unsatisfactory, ingredients statements, Nos. 2502, 2513, 2516, 2540, 2541, 2543, 2546, 2547, 2549; failure to bear a label containing an accurate statement of the quantity of the contents, Nos. 2501, 2503, 2508, 2528, 2541, 2543, 2546; failure to bear a label containing the name and place of business of the manufacturer, packer, or distributor, No. 2541; cosmetics, subject to the drug provisions of the Act, Nos. 2502 (Rensom Liquid Antiseptic Skin Lotion and Rensom Soothing Emollient), 2528 (Thi-Cin Cream and Q-2 Cream), 2540 (Yuth).

NATURE OF CHARGE: Misbranding, Section 502 (b) (2), the articles bore no label containing a statement of the quantity of the contents; Section 502 (d), they were for use by man and contained a chemical derivative of barbituric acid, which derivative had been found, by the Administrator of the Federal Security Agency, after investigation, to be and by regulation designated as habit-forming, and the label failed to bear the name and quantity or proportion of such derivative and in juxtaposition therewith, the statement "Warning—May be habit-forming"; and, Section 502 (f) (1), the labeling of the articles bore no directions for use.

DISPOSITION: July 7, 1948. A plea of nolo contendere having been entered, the court imposed a fine of $1,000 and a sentence of 1 year's imprisonment on count 1. The prison sentence was suspended for a period of 3 years and the defendant was placed on probation, conditioned that the fine be paid and that he not violate any Federal, State, or local laws. In addition, the court imposed a fine of $1,000 on count 2 of the information.

2502. Misbranding of Mo-Tee-Na Special Tablets, Vaginal Salve, Rensom Liquid Antiseptic Skin Lotion, and Rensom Soothing Emollient. U. S. v. General Products Laboratories, Inc., Frederick L. Ferguson, and Jay G. Hobson. Pleas of guilty. Fine of $400 against each defendant. (F. D. C. No. 24221. Samples Nos. 15227-H, 15228-H, 35794-H, 35795-H.)

INFORMATION FILED: February 20, 1948, Southern District of Ohio, against General Products Laboratories, Inc., Columbus, Ohio, Frederick L. Ferguson, president, and Jay G. Hobson, vice-president.

ALLEGED SHIPMENT: On or about January 16, May 17, and July 29, 1946, from the State of Ohio into the States of Illinois and Missouri.

LABEL, IN PART: "Mo Tee Na Special Tablets * * * Active Ingredients: Celery Seed, Passion Flower, Gentian, Ext. Nux Vomica ¼ grain per tablet"; "Vaginal Salve * * * Active Ingredients: Powdered Alum, Turpentine. Inactive Ingredients: Glycerin, Boric Acid, Iodine, Carbolic Acid .417% in Petrolatum Base"; "Rensom Liquid Antiseptic Skin Lotion * * * Active Ingredients: Iron Sulphate (Copperas), Boric Acid, Distilled water, Q. S."; and "Rensome Soothing Emollient * * * Active Ingredients: Red Precipitate, Zinc Oxide. Inactive Ingredients: White Petrolatum, Oil Sassafras."

NATURE OF CHARGE: *"Mo-Tee-Na Special Tablets.* Misbranding, Section 502, (a) the label statement "For Simple Nervousness, Sluggishness, and Lack of Energy Due to Overwork" was false and misleading, since the article would not be efficacious in the cure, mitigation, and treatment of simple nervousness, sluggishness, and lack of energy due to overwork.

Vaginal Salve. Misbranding, Section 502 (f) (1), the labeling of the article failed to bear adequate directions for use, since the labeling failed to state the conditions, diseases, and functions for which the article was to be used.

Rensom Liquid Antiseptic Skin Lotion. Misbranding, Section 502 (a), the label statement "Antiseptic" was false and misleading, since it represented and suggested that the article was an antiseptic, whereas it was not an antiseptic within the meaning of the law, in that it was not a germicide when used in accordance with the directions appearing in the labeling and did not purport to be, and was not represented as, an antiseptic for inhibitory use as a wet dressing, ointment, dusting powder, or such other use as involved prolonged contact with the body. Further misbranding, Section 502 (f) (1), the directions contained in the labeling for use of the article in the treatment of wounds were inadequate, in that the article would only be of value in the treatment of minor wounds when used as a wet dressing and the directions did not provide for the use of the article as a wet dressing.

Rensom Soothing Emollient. Misbranding, Section 502 (a), the label statements "Promotes Healing of Certain Skin Irritations * * * To relieve Itching and Burning of Eczema, and many similar skin irritations of external orgin" were false and misleading, since the article would not promote healing of skin irritations and would not relieve itching and burning of eczema and many similar skin irritations of external origin. Further misbranding, Section 502 (e) (2), the article was not designated solely by a name recognized in an official compendium and was fabricated from two or more ingredients, and it contained the ingredient, red precipitate, a derivative of mercury; the label of the article did not bear a statement showing the substance from which the

ingredient was derived and the fact that the ingredient was derived from mercury; and, further, the label did not bear a statement of the quantity or proportion of red precipitate contained in the article.

DISPOSITION: April 1, 1948. Pleas of guilty having been entered, the court imposed a fine of $400 against each defendant.

2503. Misbranding of Vaga-Septic Capsules and Vaga-Septic Powder. U. S. v. 30 Boxes, etc. (F. D. C. No. 25202. Sample Nos. 21746–K, 21747–K.)

LIBEL FILED: July 26, 1948, Western District of Oklahoma.

ALLEGED SHIPMENT: On or about January 26, 1948, by the Vaga-Septic Co., from Grandview, Mo.

PRODUCT: 30 boxes each containing 15 *Vaga-Septic Capsules* and 33 boxes of *Vaga-Septic Powder* at Oklahoma City, Okla. Examination showed that the capsules consisted essentially of sodium bicarbonate, borates, zinc sulfate, and oxyquinoline sulfate, and that the powder consisted essentially of boric acid, menthol, carbolic acid, aluminum sulfate, and oil of eucalyptus. Bacteriological tests showed that the powder was not antiseptic.

NATURE OF CHARGE: Misbranding, Section 502 (b) (2), the articles failed to bear labels containing an accurate statement of the quantity of the contents; Section 502 (f) (1), the labeling of the capsules failed to bear adequate directions for use, since it did not reveal the reason for using the article; and, Section 502 (a), the statements "Vaga-Septic" and "Healing" on the label of the powder were false and misleading, since the article was not antiseptic and was not effective in healing.

DISPOSITION: September 3, 1948. Default decree of condemnation and destruction.

2504. Misbranding of Brother Tom's Medicine and iron and yeast tablets. U. S. v. 14 Packages * * *. (F. D. C. No. 25144. Sample Nos. 36262–K, 36263–K.)

LIBEL FILED: August 5, 1948, District of Montana.

ALLEGED SHIPMENT: On or about June 11, 1948, by the Brother Tom's Medicine Co., from Los Angeles, Calif.

PRODUCT: 14 packages of *Brother Tom's Medicine*, at Butte, Mont., each package containing 1 bottle of the medicine and an envelope containing *iron and yeast tablets*.

LABEL, IN PART: (Bottle) "Liquid Medicine That Acts as a Laxative, Stomachic, Carminative, Diuretic. Contains the active principles extracted from Cascara Sagrada, Senna, Gentian, Fennel Seed, and in addition contains Aloin, Caffeine, Sodium Benzoate, Salicylic Acid and flavoring ingredients"; (envelope) "Iron and Yeast Tablets * * * Four Tablets Contain Iron 75 Mg. (Ferrous Sulf. Exsic. 3.9 Gr.) Yeast 12 Gr. (Primary Dried U. S. P.) B_1 (Thiamin) 1.8 Mg. with excipients and fillers."

NATURE OF CHARGE: *Brother Tom's Medicine.* Misbranding, Section 502 (f) (1), the labeling of the article failed to bear adequate directions for use as a stomachic, carminative, and diuretic, the purposes for which it was recommended in its labeling.

Iron and yeast tablets. Misbranding, Section 502 (a), certain statements in a circular enclosed in the envelope containing the tablets were false and misleading. These statements suggested and implied that the tablets would preserve a lady's beauty and prevent her face from growing pale when her freshness was lagging and her energy was low; that they would remedy puny, weak, red blood cells, enabling them to send full energy into one's system; that they would build energy; that they would correct tired, listless, pale conditions, and would cause the red cells to release energy to the body; and that they would favorably affect puny, faded cells, enabling them to release needed energy and cause one to look and feel his best. The tablets would not be effective for such purposes.

DISPOSITION: September 21, 1948. Default decree of condemnation and destruction.

2505. Misbranding of Vit-An-Min. U. S. v. 310 Bottles, etc. (F. D. C. No. 25081. Sample Nos. 19460–K, 19461–K.)

LIBEL FILED: July 13, 1948, Northern District of Ohio.

ALLEGED SHIPMENT: On or about June 8 and 15, 1948, by S. & R. Laboratories, Inc., from Chicago, Ill.

PRODUCT: 310 12-ounce bottles of *Vit-An-Min* at Toledo, Ohio, together with 1,300 circulars entitled "Add to Your Diet with Vit-An-Min." Sales of this product were made on the basis of lectures given at the store of the consignee by Edward S. Haller, a representative of the S. & R. Laboratories, Inc. Examination showed that the product was an orange, powdered material containing calcium, phosphorus, and iron.

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements in the circulars were false and misleading. These statements represented and suggested that common food cannot be relied upon to supply the vitamins and minerals essential to man for normal health, and that it is necessary to add the article to your diet. There is no difficulty in obtaining the vitamins and minerals needed by the consumption of common foods.

Further misbranding, Section 502 (f) (1), the labeling of the article failed to bear adequate directions for use in the treatment of nervous and ulcerated stomach, arthritis, neuritis, rheumatism, anemia, underweight, and overweight, and to obviate the need for changes in eyeglasses, which were the diseases, symptoms, and conditions for which the article was offered in its advertising disseminated and sponsored by or on behalf of the manufacturer, packer, or distributor.

DISPOSITION: August 30, 1948. Default decree of condemnation and destruction.

2506. Misbranding of Cravex. U. S. v. 35 Small Cartons, etc. (F. D. C. No. 25136. Sample No. 756–K.)

LIBEL FILED: August 19, 1948, Southern District of Florida.

ALLEGED SHIPMENT: On or about May 8, 1948, by Plant Products Co., Inc., from Burbank, Calif.

PRODUCT: 35 small and 11 large cartons of *Cravex* at Jacksonville, Fla.

NATURE OF CHARGE: Misbranding, Section 502 (f) (1), the labeling of the article failed to bear adequate direction for use, since it failed to reveal the reason for its use as directed in the labeling, namely, "one powder twice daily in food or liquid."

DISPOSITION: October 26, 1948. Default decree of condemnation and destruction.

2507. Misbranding of Spectro-Chrome. U. S. v. 1 Device * * * (and 5 other seizure actions). (F. D. C. Nos. 25038, 25121, 25122, 25200, 25209, 25210. Sample Nos. 6691–K, 15219–K, 15220–K to 15222–K, incl., 31620–K.)

LIBELS FILED: July 15, 23, and 30, and September 13, 1948, Western District of New York, Northern District of Illinois, and Southern District of California.

ALLEGED SHIPMENT: On or about December 8, 1947, and February 9 and March 1 and 26, 1948, by the Dinshah Spectro-Chrome Institute, from Malaga, N. J.

PRODUCT: 6 *Spectro-Chrome* devices at Lackawanna, N. Y., Blue Island, Chicago, and Rockford, Ill., and Redlands, Calif. The device consisted of a cabinet equipped with a 1,000-watt floodlight bulb, an electric fan, a container for water for cooling purposes, two glass condenser lenses for concentrating the light, and glass slides of different colors.

NATURE OF CHARGE: Misbranding, Section 502 (f) (1), the labeling of the article failed to bear adequate directions for use for the purposes for which it was intended.

DISPOSITION: August 16, September 14, and October 5 and 12, 1948. Default decrees of condemnation and destruction.

DRUGS ACTIONABLE BECAUSE OF CONTAMINATION WITH FILTH

2508. Adulteration and misbranding of Scheuerman's Herb Compound No. 1. U. S. v. Charles Scheuerman. Plea of guilty. Sentence of 1 year and 1 day on each count, to run concurrently; sentence suspended and defendant placed on probation for 1 year and 1 day. (F. D. C. No. 24248. Sample Nos. 63636–H, 68819–H.)

INDICTMENT RETURNED: July 9, 1948, Southern District of Ohio, against Charles Scheuerman, Cincinnati, Ohio.

ALLEGED SHIPMENT: On or about April 17, 1946, and March 22, 1947, from the State of Ohio into the States of New York and Illinois.

NATURE OF CHARGE: Adulteration, Section 501 (a) (1), the article consisted in part of a filthy substance by reason of the presence of insect fragments and rotten and moldy plant material; and, Section 501 (a) (2), it had been prepared and packed under insanitary conditions whereby it may have become contaminated with filth.

Misbranding, Section 502 (b) (2), the article in the April 17, 1946, shipment failed to bear a label containing an accurate statement of the quantity of the contents, in that the label affixed to the bottle bore no statement of the quantity of the contents.

DISPOSITION: July 21, 1948. A plea of guilty having been entered, the court sentenced the defendant to serve 1 year and 1 day on each of the 3 counts of the information, with the sentence on each count to run concurrently. The sentence was suspended and the defendant was placed on probation for 1 year and 1 day.

2509. Adulteration of chamomile flowers. U. S. v. 35 Bags, etc. (F. D. C. No. 25089. Sample No. 9934–K.)

LIBEL FILED: July 14, 1948, Southern District of New York.

ALLEGED SHIPMENT: From the country of Hungary to New York, N. Y. The product was received in New York on May 15, 1947.

PRODUCT: 35 bags containing a total of 2,010 pounds and 34 cases containing a total of 3,967 pounds of *chamomile flowers* at New York, N. Y.

NATURE OF CHARGE: Adulteration, Section 501 (a) (1), the article consisted in whole or in part of a filthy substance by reason of the presence of insects. The article was adulterated while held for sale after shipment in interstate commerce.

DISPOSITION: September 7, 1948, The Meer Corporation, New York, N. Y., claimant, having consented to the entry of a decree, judgment of condemnation was entered and the product was ordered released under bond for cleaning, fumigating, and sifting, under the supervision of the Federal Security Agency.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF DEVIATION FROM OFFICIAL OR OWN STANDARDS*

2510. Adulteration of triple distilled water, solution anterior pituitary, ovarian extract, and ampuls of sodium iodide. U. S. v. Torigian Laboratories, Inc., and John Torigian. Plea of guilty for corporation on all four counts and plea of guilty for individual on count 1. Fine of $1,000 against corporation; individual fined $800 on count 1 and placed on probation for two years. Counts 2, 3, and 4 against individual dismissed. (F. D. C. No. 17881. Sample Nos. 78856–F, 87034–F, 16512–H, 16514–H, 16520–H.)

INFORMATION FILED: March 17, 1947, Eastern District of New York, against the Torigian Laboratories, Inc., Queens Village, New York, N. Y., and John Torigian, president of the corporation.

ALLEGED SHIPMENT: On or about July 15, August 30, and December 12, 1944, and January 26, 1945, from the State of New York into the States of Michigan and Illinois.

NATURE OF CHARGE: *Triple distilled water.* Adulteration, Section 501 (b), the article purported to be and was represented as "Water for Injection," a drug the name of which is recognized in the United States Pharmacopoeia, an official compendium, and its quality and purity fell below the official standard by reason of the presence of undissolved material and pyrogens; and the difference in quality and purity of the article from the official standard was not plainly stated, or stated at all, on its label.

Solution anterior pituitary and ovarian extract. Adulteration, Section 501 (b), the purity and quality of the articles fell below that which they purported and were represented to possess. They purported and were represented to be of a purity and quality suitable and appropriate for intramuscular injection and use, which use requires a sterile product. The articles were not of such purity or quality, since they were not sterile and were contaminated with living micro-organisms.

Ampuls of sodium iodide. Adulteration, Section 501 (b), the article purported to be and was represented as "Ampuls of Sodium Iodide," a drug the

*See also Nos. 2547, 2548 (veterinary preparations).

name of which is recognized in the National Formulary, an official compendium, and its quality and purity fell below the official standard since it contained undissolved material; and the difference in quality and purity of the article from the official standard was not plainly stated, or stated at all, on its label.

DISPOSITION: June 24, 1948. A plea of guilty was entered on behalf of the corporation to all 4 counts of the information, and a plea of guilty was entered by the individual to count 1 of the information relating to the triple distilled water. The corporation was fined $250 on each of the 4 counts; the individual was fined $800 on count 1 and placed on probation for two years. Counts 2, 3, and 4 of the information were dismissed with respect to the individual.

2511. Adulteration of phenobarbital tablets and misbranding of nicotinic acid tablets and sodium iodide solution. U. S. v. California Pharmacal Co., Augustin J. Bellport, Jr., and Herbert C. Skinner. Pleas of nolo contendere. Fine of $750 against company. Imposition of sentence against individual defendants suspended for two years and these defendants placed on probation. (F. D. C. No. 24270. Sample Nos. 18410–K, 18413–K, 18416–K.)

INFORMATION FILED: June 28, 1948, Southern District of California, against the California Pharmacal Co., a corporation, Los Angeles, Calif., and Augustin J. Bellport, Jr., president, and Herbert C. Skinner, vice-president.

ALLEGED SHIPMENT: On or about January 7, February 7, and September 9, 1947, from the State of California into the State of Ohio.

NATURE OF CHARGE: *Phenobarbital tablets.* Adulteration, Section 501 (b), the article purported to be and was represented as "Phenobarbital Tablets," a drug the name of which is recognized in the United States Pharmacopoeia, and its strength differed from the official standard since it contained more than 106 percent of the labeled amount of phenobarbital, the maximum permitted by the standard; and its difference in strength from the standard was not plainly stated, or stated at all, on its labeling.

Nicotinic acid tablets. Misbranding, Section 502 (a), the label statement "C. T. Nicotinic Acid 50 mg." was false and misleading. This statement represented and suggested that each tablet of the article contained 50 milligrams of nicotinic acid, whereas each tablet of the article contained less than 50 milligrams of nicotinic acid.

Sodium iodide solution. Misbranding, Section 502 (a), the label statement "Sodium Iodide 10% * * * Each 10cc contains 15.5 grains (1.0 gm.) of Sodium Iodide" was false and misleading. This statement represented and suggested that 10 cc. of the article contained 15.5 grains or 1 gram of sodium iodide, whereas 10 cc. of the article contained less than 15.5 grains or 1 gram of sodium iodide.

DISPOSITION: August 9, 1948. Pleas of nolo contendere having been entered, the court imposed a fine of $750 against the corporation and suspended the imposition of sentence against the individuals for 2 years and placed them on probation.

2512. Adulteration and misbranding of Urginin tablets. U. S. v. Grisard Laboratories, Inc. Plea of guilty. Fine of $200 and costs. (F. D. C. No. 23264. Sample No. 83102–H.)

INFORMATION FILED: December 23, 1947, Eastern District of Tennessee, against Grisard Laboratories, Inc., Winchester, Tenn.

ALLEGED SHIPMENT: On or about March 3, 1947, from the State of Tennessee into the State of Kentucky.

LABEL, IN PART: "Tablets Salicyline No. 2. Enteric Coated. Kendall." Squill."

NATURE OF CHARGE: Adulteration, Section 501 (c), the strength of the article differed from that which it was represented to possess, in that each tablet of the drug was represented to contain an amount of the cardio-active glycosides of squill equivalent in potency to 2.5 "cat units" of digitalis, as determined by the test for tincture of digitalis set forth in the United States Pharmacopoeia, Twelfth Revision, whereas the article possessed a potency equivalent to not more than 1.55 "cat units" of digitalis, which was not more than 62 percent of the declared potency.

Misbranding, Section 502 (a), the label statements (carton) "Contains Two Of The Cardio-Active Glycosides Of Squill * * * Standardized by the U. S. P. XII Cat Method. Each tablet * * * Is Equivalent To 2.5 Cat

Units" and (bottle) "Standardized Cardio-Active Glycosides Of Squill * * * Each tablet is equal to 2.5 Cat Units as standardized by the U. S. P. Cat Method" were false and misleading, since the article when tested in accordance with the method set forth in the United States Pharmacopoeia, Twelfth Revision, for tincture of digitalis did not contain an amount of the cardio-active glycosides of squill equivalent in potency to 2.5 "cat units" of digitalis but possessed a lesser potency.

DISPOSITION: April 16, 1948. A plea of guilty having been entered, the defendant was fined $200, together with costs.

2513. Adulteration and misbranding of Oleum Paracamphine, adulteration of thiamine hydrochloride tablets, and misbranding of Astringodyne. U. S. v. Saint Louis Pharmacal Co. Plea of nolo contendere. Fine, $400. (F. D. C. No. 24073. Sample Nos. 40754–H, 53627–H, 53628–H.)

INFORMATION FILED: January 26, 1948, Eastern District of Missouri, against the Saint Louis Pharmacal Co., a corporation, St. Louis, Mo.

ALLEGED SHIPMENT: On or about April 20, September 30, and October 9, 1946, from the State of Missouri into the States of Illinois and Indiana.

NATURE OF CHARGE: *Oleum Paracamphine.* Adulteration, Section 501 (c), the quality of the article fell below that which it purported and was represented to possess. It was represented as an antiseptic, whereas it was not an antiseptic. Misbranding, Section 502 (a), the label statement "An Antiseptic" was false and misleading, since the article was not an antiseptic; and, Section 502 (e) (2), the article was not designated solely by a name recognized in an official compendium and was fabricated from two or more ingredients, and its label failed to bear the common or usual name of each active ingredient.

Thiamine hydrochloride tablets. Adulteration, Section 501 (c), the strength of the article differed from, and its quality fell below, that which it purported and was represented to possess, since it purported and was represented to contain 5 mgms. of thiamine hydrochloride in each tablet, whereas it contained a smaller amount.

Astringodyne. Misbranding, Section 502 (a), the label statements "Containing Zinc Iodide . . . 0.46%," "Iodine . . . 0.6," "Ephedrine, alkaloid . . . 1" were false and misleading, since the article contained no iodine and contained materially less than 0.46 percent of zinc iodide and 1 percent of ephedrine alkaloid.

DISPOSITION: October 29, 1948. A plea of nolo contendere having been entered, the court imposed a fine of $400.

2514. Adulteration and misbranding of Salicyline tablets. U. S. v. C. B. Kendall Co., Inc., and Claude B. Kendall. Pleas of guilty. Fine of $150 against each defendant. (F. D. C. No. 24227. Sample Nos. 83126–H, 83151–H.)

INFORMATION FILED: July 12, 1948, Southern District of Indiana, against C. B. Kendall Co., Inc., Indianapolis, Ind., and Claud B. Kendall, president of the corporation.

ALLEGED SHIPMENT: On or about May 15, 1947, from the State of Indiana into the State of Kentucky.

LABEL, IN PART: "Tablets Salicyline No. 2. Enteric Coated. Kendall."

NATURE OF CHARGE: Adulteration, Section 501 (c), the strength of the article differed from that which it purported and was represented to possess. Each tablet of the article was represented to contain 3 milligrams of thiamine hydrochloride, equivalent to 1,000 International Units of vitamin B_1, and to contain 5,000 units of vitamin D. Each tablet contained less thiamine hydrochloride and less vitamin D than represented.

Misbranding, Section 502 (a), the label statement "Each Tablet Contains: * * * Thiamine Hydrochloride 3 mg. (1000 International Units B_1) Vitamin D . . . 5000 Units" was false and misleading.

DISPOSITION: November 26, 1948. Pleas of guilty having been entered, the court imposed a fine of $150 against each defendant.

2515. Adulteration and misbranding of Viblex. U. S. v. Ray F. McMullin (Endocrine Products Laboratory), and Walter E. Sterz. Pleas of nolo contendere. Fines, $51 against Ray F. McMullin and $2 against Walter E. Sterz. (F. D. C. No. 24283. Sample No. 36468–K.)

INFORMATION FILED: September 3, 1948, Southern District of California, against Ray F. McMullin, trading as Endocrine Products Laboratory, Los Angeles, Calif., and Walter E. Sterz, a pharmacist for the laboratory.

ALLEGED SHIPMENT: On or about January 23, 1948, from the State of California into the State of Washington.

NATURE OF CHARGE: Adulteration, Section 501 (c), the strength of the article differed from that which it was represented to possess, since each cubic centimeter of the article was represented to contain 2 milligrams of riboflavin, 100 milligrams of niacinamide, and 50 milligrams of thiamine hydrochloride, whereas each cubic centimeter of the article contained less than those amounts of riboflavin, niacinamide, and thiamine hydrochloride.

Misbranding, Section 502 (a), the label statements "Each cc. Contains Riboflavin (B_2) . . . 2 milligrams * * * Niacinamide . . . 100 milligrams Thiamine Hydrochloride . . . 50 milligrams" were false and misleading.

DISPOSITION: November 29, 1948. Pleas of nolo contendere having been entered, the court imposed fines of $51 and $2 against Ray F. McMullin and Walter E. Sterz, respectively.

2516. Adulteration and misbranding of Millard's Triple Prescription Formula Tablets No. 1 and misbranding of Millard's Triple Prescription Formula Tablets No. 2 and No. 3. U. S. v. The Millard Co. and Millard H. Krasne. Pleas of guilty. Fines of $120 against the company and $80 against the individual, together with costs. (F. D. C. No. 24260. Sample Nos. 68556–H, 99645–H.)

INFORMATION FILED: July 9, 1948, Southern District of Iowa, against the Millard Co., a partnership, Council Bluffs, Iowa, and Millard H. Krasne, a member of the partnership.

ALLEGED SHIPMENT: On or about May 21 and June 25, 1947, from the State of Iowa into the States of Missouri and Nebraska.

PRODUCT: Analyses disclosed that the *Tablets No. 1* in the May 21 shipment were compressed white tablets consisting essentially of acetylsalicylic acid; that the *Tablets No. 2* in that shipment were brown-coated tablets consisting chiefly of phenolphthalein and aloin; that the *Tablets No. 1* in the June 25 shipment were white compressed tablets containing much less than the declared amounts of caffeine and aspirin and more than the declared amount of acetophenetidin; and that the *Tablets No. 2* in the latter shipment consisted of brown-coated tablets containing chiefly phenolphthalein, aloin, podophyllin, and calcium carbonate. The composition of the *Tablets No. 3* agreed substantially with the label declaration.

LABEL, IN PART: "Tablets No. 1 * * * Contains: 5 Gr. Acetosalicylic Acid, 2 Gr. Caffeine, 1½ Gr. Acetophenitidin," "Tablets No. 2 * * * Contains: Aloin, Podophyllin, Sodium Salicylate, Ginger extract of Belladonna," and "Tablets No. 3 * * * Contains: Carotene, Thiamin Hydrochloride, Ascorbic Acid, Riboflavin, Calcium Pantothenate, Nicotinamide, and Pyroxidine."

NATURE OF CHARGE: *Tablets No. 1.* Adulteration, Section 501 (c), the strength of the tablets differered from that which they purported and were represented to possess. The tablets purported and were represented to contain 5 grains of acetylsalicylic acid, 2 grains of caffeine, and 1½ grains of acetophenetidin, whereas the tablets in the May 21 shipment contained less than 2 grains of caffeine and less than 1½ grains of acetophenetidin and the tablets in the June 25 shipment contained less than 5 grains of acetylsalicylic acid, less than 2 grains of caffeine, and more than 1¼ grains of acetophenetidin. Misbranding, Section 502 (a), certain statements in the labeling of the article which represented and suggested that each tablet contained 5 grains of acetylsalicylic acid, 2 grains of caffeine, and 1¼ grains of acetophenetidin, were false and misleading. Further misbranding, Section 502 (a), certain statements in the labeling of the article, which included an enclosed booklet entitled "I Hope Sincerely That My Medicines Relieve Your Pains Promptly," were false and misleading. Such statements represented and suggested that the article would be effective to relieve congestion; that when used in conjunction with *Tablets No. 2* and *Tablets No. 3*, it would be effective to eliminate pain caused by rheumatism, arthritis, neuritis, sciatica, and leg cramp, and to improve health, vigor, and endurance; and that when used in conjunction with *Tablets No. 2*, it would be effective to activate the liver, to produce more bile, and to improve assimilation. The article would not be effective for such purposes.

Tablets No. 2. Misbranding, Section 502 (a), a statement in the labeling that the article contained sodium salicylate was false and misleading, since

the article contained no sodium salicylate; and certain statements in the labeling, which included the enclosed booklet referred to above, were false and misleading, since the statements represented and suggested that the article when used in conjunction with *Tablets No. 1* and *Tablets No. 3* would be effective to eliminate pain caused by rheumatism, arthritis, neuritis, sciatica, and leg cramp, and to improve health, vigor, and endurance; that when used alone and in conjunction with *Tablets No. 1*, it would be effective to activate the liver, to produce more bile, and to improve assimilation; and that when used with *Tablets No. 3*, it would be effective to maintain normal health. The article would not be effective for such purposes. Further misbranding, Section 502 (e) (2), the article was not designated solely by a name recognized in an official compendium and was fabricated from two or more ingredients; its label failed to bear the common or usual name of each active ingredient since the article contained as one of its active ingredients, phenolphthalein, and the label failed to declare the presence of phenolphthalein; and the article contained the alkaloids of atropine, hyoscine, and hyoscyamine, as constituents of belladonna, and its label did not bear the name and quantity or proportion of the said alkaloids, nor did the label bear, in lieu thereof, the quantity or proportion of the total alkaloids contained as constituents of belladonna.

Tablets No. 3. Misbranding, Section 502 (a), certain statements in the labeling of the article, which included the above-mentioned booklet, were false and misleading. Such statements represented and suggested that the article when used in conjunction with *Tablets No. 1* and *Tablets No. 2*, would be effective to eliminate pains caused by rheumatism, arthritis, neuritis, sciatica, and leg cramp; that when used alone and in conjunction with the other tablets, the article would be effective to improve health, vigor, and endurance; and that when used in conjunction with *Tablets No. 2*, it would be effective to maintain normal health. The article would not be effective for such purposes.

DISPOSITION: September 24, 1948. Pleas of guilty having been entered, the court imposed a fine of $120 against the partnership and $80 against the individual, together with costs.

2517. Adulteration and misbranding of Cal-Par. U. S. v. Hood Products Corp. and Charles H. Fingerhood. Pleas of guilty. Fine of $1,000 against defendants jointly. (F. D. C. No. 6504. Sample No. 61018-E.)

INFORMATION FILED: April 6, 1944, Southern District of New York, against the Hood Products Corp., New York, N. Y., and Charles H. Fingerhood, an officer of the corporation.

ALLEGED SHIPMENT: Between May 10 and 14, 1941, from the State of New York into the State of Washington.

PRODUCT: Microscopic examination showed that the product contained wheat germ, wheat bran, wheat flour, and crystalline material. It contained also compounds of calcium and iron.

NATURE OF CHARGE: Adulteration, Section 501 (c), the strength of the article differed from, and its quality fell below, that which it purported and was represented to possess. The article was represented to contain 1.8 grams of phosphorus per two heaping teaspoonfuls, whereas it contained not more than 0.476 gram of phosphorus per two heaping teaspoonfuls.

Misbranding, Section 502 (a), the label statement "Two Heaping Teaspoonfuls supply approximately * * * 1.8 Grams of Phosphorus" was false and misleading, since the article contained not more than 0.476 gram of phosphorus per two heaping teaspoonfuls.

Further misbranding, Section 502 (a), certain statements on the label and in an accompanying leaflet, circular, and display card, were false and misleading. These statements represented and suggested that the article when used as directed by a specified plan, would be efficacious in reducing weight; that it would supply the average person's daily needs of phosphorus; that by supplying calcium it would promote strong teeth, sturdy bones, firm flesh, and pliant muscles; that by supplying phosphorus it would promote the most highly efficient brain cells; that by supplying iron it would aid the red corpuscles of the body to function; that the article would supply the necessary elements of nutrition to increase weight; that the daily use of the article would supply

the amount of calcium, phosphorus, iron, and vitamin D required daily by the average person; that the article would bring the body of an underweight person up to normal; that when a reducing diet was used, the article would supply the calcium, phosphorus, iron, and vitamin D, and the necessary additional quantities of the vitamins A, B_1, and G, which the body requires because of the reduction in calories which results from the reducing diet; that when a reducing diet was used, the article when administered in accordance with the Cal-Par Reducing Plan for Eating, would prevent nervousness, tiredness, sleeplessness, and lack of pep and vigor by supplying the body's daily requirements of calcium, phosphorus, iron, and vitamin D; that the use of the article in the absence of glandular or organic complications, would take off surplus fat; that two heaping teaspoonfuls taken daily would supply the average person's daily requirements of phosphorus; that the article was a necessary part of practically every reducing diet; that it would prevent the undermining of health of persons following a reducing diet; that it would enable persons to reduce easily with no undue hardship; that it would help to build sturdy bones and strong teeth; that if used daily, it would supply the amounts of calcium, phosphorus, iron, and vitamin D to bring the body of underweight persons up to normal; that the use of the article in accordance with a specified 7-day reducing plan, would cause the loss of at least 8 pounds per week; that when used in accordance with a specified special reducing plan, the article would cause the body to lose as much as 18 pounds in 12 days; that the article would supply mineral and vitamin deficiencies to the system; that it would supply necessary minerals and vitamins to the system and thereby prevent heart trouble, nervous disorders, kidney ailments, liver ailments, digestive upsets, eye afflictions, and many other ailments which may be a direct result of a lack of certain vitamins and minerals; that it would prevent ailments of the teeth and bones and decay of the teeth by supplying calcium; that it would help in the building of strong teeth and firm bones, in aiding the blood to keep its proper balance between acidity and alkalinity, and in nourishing the nerves and brain; that it would be efficacious in the cure, mitigation, treatment, or prevention of anemic, rundown conditions; that it would be of great advantage to build up resistance to disease; that the use of the article by women during pregnancy would cause the child to be born well-formed and in good health; and that the use of the article would be efficacious in the cure, mitigation, treatment, or prevention of sinus trouble, rheumatism, and arthritis. The article would not fulfill the promises of benefit stated and implied.

The article was alleged also to be adulterated and misbranded under the provisions of the law applicable to foods, as reported in notices of judgment on foods.

DISPOSITION: October 8, 1948. Pleas of guilty having been entered, the court imposed a fine of $1,000 against the defendants jointly.

2518. Adulteration of isotonic solution of sodium chloride. U. S. v. 22 Cartons * * *. (F. D. C. No. 25353. Sample No. 1043–K.)

LIBEL FILED: August 10, 1948, Southern District of Florida.

ALLEGED SHIPMENT: On or about January 28, 1948, from Cleveland, Ohio.

PRODUCT: 22 cartons, each containing 6 1,000-cc. flasks, of *isotonic solution of sodium chloride*. The product was contained in hermetically sealed flasks and was intended for intravenous injection.

NATURE OF CHARGE: Adulteration, Section 501 (b), the article purported to be and was represented as "Sterile Isotonic Sodium Chloride Solution for Parenteral Use," a drug the name of which is recognized in the United States Pharmacopoeia, an official compendium, and its quality and purity fell below the official standard, since it was contaminated with undissolved material. The article was adulterated while held for sale after shipment in interstate commerce.

DISPOSITION: November 12, 1948. Default decree of forfeiture and destruction.

2519. Adulteration of isotonic solution of three chlorides and isotonic solution of sodium chloride. U. S. v. 54 Flasks, etc. (F. D. C. No. 25344. Sample Nos. 10603–K, 10608–K.)

LIBEL FILED: August 5, 1948, District of New Jersey.

ALLEGED SHIPMENT: On or about June 21 and 30, 1948, by the Continental Pharmacal Co., from Cleveland, Ohio.

PRODUCT: 54 500-cc. flasks of *isotonic solution of three chlorides* and 12 1,000-cc. flasks of *isotonic solution of sodium chloride* at Elizabeth, N. J.

NATURE OF CHARGE: Adulteration, Section 501 (b), the articles purported to be and were represented as "Sterile Ringer's Solution for Parenteral Use" and "Sterile Isotonic Sodium Chloride Solution for Parenteral Use," drugs the names of which are recognized in the United States Pharmacopoeia, an official compendium, and their quality and purity fell below the official standard, since they were not substantially free of any turbidity and undissolved material, as required by the Pharmacopoeia, but were contaminated with undissolved material.

DISPOSITION: November 8, 1948. Default decree of condemnation. The products were ordered delivered to the Food and Drug Administration, for official purposes.

2520. Adulteration of solution of sodium chloride. U. S. v. 6 Cases * * *. (F. D. C. No. 25345. Sample No. 9385–K.)

LIBEL FILED: August 6, 1948, Southern District of New York.

ALLEGED SHIPMENT: On or about April 27, 1948, by the Continental Pharmacal Co., from Cleveland, Ohio.

PRODUCT: 6 cases, each containing 12 flasks, of solution of *sodium chloride* at New York, N. Y. The product was intended for intravenous injection, as evidenced by the statement on the flask label "For the purpose of filling and rinsing the tubing this unit contains 50 cc. in excess of the declared volume."

LABEL, IN PART: "Sodium Chloride 5% in Distilled Water 500 cc."

NATURE OF CHARGE: Adulteration, Section 501 (c), the purity and quality of the article fell below that which it purported and was represented to possess since it contained undissolved material, whereas an article which is represented for intravenous use should be substantially free of any undissolved material.

DISPOSITION: August 27, 1948. Default decree of condemnation and destruction.

2521. Adulteration and misbranding of A-C-D anticoagulant acid citrate dextrose. U. S. v. 18 Flasks * * *. (F. D. C. No. 25346. Sample No. 10602–K.)

LIBEL FILED: August 5, 1948, District of New Jersey.

ALLEGED SHIPMENT: On or about June 18, 1947, by the Continental Pharmacal Co., from Cleveland, Ohio.

PRODUCT: 18 55-cc. flasks of *A–C–D anticoagulant acid citrate dextrose* at Elizabeth, N. J.

NATURE OF CHARGE: Adulteration, Section 501 (b), the article purported to be and was represented as "Anticoagulant Acid Citrate Dextrose," a drug the name of which is recognized in the United States Pharmacopoeia, and its quality fell below the official standard since it was pyrogenic and contaminated with undissolved material.

Misbranding, Section 502 (a), the label statement "This product is * * * non-pyrogenic" was false and misleading as applied to this article, which contained pyrogen.

DISPOSITION: November 8, 1948. Default decree of condemnation. The product was ordered delivered to the Food and Drug Administration, for official purposes.

2522. Adulteration of ampuls of sodium iodide. U. S. v. 11,940 * * * Ampuls etc. (F. D. C. No. 25085. Sample Nos. 10575–K to 10578–K, incl.)

LIBEL FILED: July 13, 1948, Eastern District of New York.

ALLEGED SHIPMENT: On or about April 21, 1948, by the Veterans Administration Supply Depot, from Broadview, Ill. This was a return shipment.

PRODUCT: 11,940 20-cc. ampuls and 33,075 10-cc. *ampuls of sodium iodide* at Long Island City, N. Y.

LABEL, IN PART: "20 cc. + Ampule Sodium Iodide 10% W/V Intravenous," or "10 cc. Ampul Sodium Iodide 2 grams for Intravenous Use."

NATURE OF CHARGE: Adulteration, Section 501 (b), the article purported to be and was represented as "Ampuls of Sodium Iodide," a drug the name of which is recognized in the National Formulary, an official compendium, and its quality and purity fell below the official standard since it was contaminated with undissolved material.

DISPOSITION: September 28, 1948. Default decree of condemnation and destruction.

2523. Adulteration and misbranding of estrogenic hormone. U. S. v. 1 Bottle * * *. (F. D. C. No. 24328. Sample No. 18025–K.)

LIBEL FILED: February 10, 1948, Southern District of Indiana.

ALLEGED SHIPMENT: On or about November 18, 1947, by Hema Drug Co., Inc., from Maspeth, N. Y.

PRODUCT: 1 bottle containing 3 liters of *estrogenic hormone* at Indianapolis, Ind. Examination showed that each cubic centimeter of the article contained 0.78 milligram of ketones calculated as estrone.

LABEL, IN PART: "Whole Natural Estrogenic Hormone in Propylene Glyco."

NATURE OF CHARGE: Adulteration, Section 501 (c), the strength of the article differed from that which it purported and was represented to possess, i. e., "Whole Natural Estrogenic Hormone * * * consisting of estrone with small amounts of auxiliary hormones, each cc equivalent to 20,000 international unit of estrone. Minimum ketone content 90–95%."

Misbranding, Section 502 (a), the above-quoted label statement was false and misleading, since the article did not have the composition represented and implied thereby.

DISPOSITION: November 1, 1948. Default decree of forfeiture and destruction.

2524. Adulteration and misbranding of Aquadiol. U. S. v. 23 Vials * * *. (F. D. C. No. 25124. Sample No. 255–K.)

LIBEL FILED: July 27, 1948, Eastern District of Pennsylvania.

ALLEGED SHIPMENT: On or about June 17, 1948, by the National Drug Co., from Atlanta, Ga.

PRODUCT: 23 vials of *Aquadiol* at Philadelphia, Pa. Examination showed that the product contained less than 0.13 milligram of alpha estradiol per cubic centimeter.

LABEL, IN PART: (Vial) "25 cc. Aquadiol * * * Estrogenic Hormone containing per cc. 0.22 mg. alpha Estradiol."

NATURE OF CHARGE: Adulteration, Section 501 (c), the strength of the article differed from that which it was represented to possess, i. e., 0.22 milligram of alpha estradiol per cubic centimeter.

Misbranding, Section 502 (a), the label statement "per cc. 0.22 mg. alpha estradiol" was false and misleading.

DISPOSITION: September 14, 1948. Default decree of condemnation and destruction.

2525. Adulteration of phenobarbital tablets. U. S. v. 14 Drums * * *. (F. D. C. No. 24846. Sample Nos. 18498–K, 18499–K, 18787–K, 18788–K.)

LIBEL FILED: May 21, 1948, Southern District of Ohio.

ALLEGED SHIPMENT: On or about February 27 and March 12, 1948, by Clark-Babbitt Pharmaceutical Labs., Inc., from Boston, Mass.

PRODUCT: *Phenobarbital tablets.* 8 drums containing a total of 400,000 tablets and 6 drums containing a total of about 388,525 tablets at Gallipolis, Ohio.

LABEL, IN PART: "C. T. Phenobarbital 1½ gr."

NATURE OF CHARGE: Adulteration, Section 501 (b), the article purported to be and was represented as "Phenobarbital Tablets," a drug the name of which is recognized in the United States Pharmacopoeia, and its strength differed from the official standard, since a portion of the tablets contained less than the declared amount of phenobarbital and the remainder of the tablets contained more than the declared amount of phenobarbital. (The tablets in the 8-drum lot contained less than 80 percent of the declared amount of phenobartital; the tablets in 1 drum of the 6-drum lot contained not more than 92 percent; and those in the remaining 5 drums contained more than 109 percent of the labeled amount of phenobarbital. The Pharmacopoeia requires that *phenobarbital tablets* contain not less than 94 percent, and not more than 106 percent, of the labeled amount of phenobarbital.)

DISPOSITION: July 29, 1948. Default decree of destruction.

2526. Adulteration and misbranding of phenobarbital sodium tablets and misbranding of atropine sulfate tablets. U. S. v. 95 Bottles, etc. (F. D. C. No. 24838. Sample Nos. 10221-K, 10223-K.)

LIBEL FILED: May 12, 1948, District of New Jersey.

ALLEGED SHIPMENT: On or about December 12, 1947, and January 7, 1948, from Long Island City, N. Y. The *phenobarbital sodium tablets* were shipped by Cole Laboratories, Inc., and the *atropine sulfate tablets* were shipped by the Retort Pharmaceutical Co., Inc., a wholly owned subsidiary of Cole Laboratories, Inc.

PRODUCT: 214 bottles of *phenobarbital sodium tablets* and 1,940 tubes of *atropine sulfate tablets* at Royce, N. J. Examination showed that each bottle of the *phenobarbital sodium tablets* contained less than half the declared number of whole tablets, together with broken and disintegrated tablets; and that each of the whole tablets contained 1.7 grains of phenobarbital sodium. Examination of 30 tubes of *atropine sulfate tablets* showed that they contained from 20 whole tablets to as few as 9 whole tablets per tube, with the entire 30 tubes containing 543 whole tablets, together with broken, chipped, and powdered tablets.

LABEL, IN PART: "1000 Hypodermic Tablets each tablet contains 2 grains (0.12 gm.) Phenobarbital Sodium U. S. P.," and "20 Hypodermic Tablets 1/150 Gr. each Atropine Sulphate U. S. P."

NATURE OF CHARGE: *Phenobarbital sodium tablets.* Adulteration, Section 501 (b), the strength of the article differed from the official standard. The United States Pharmacopoeia requires that sodium phenobarbital tablets contain not less than 90 percent of the labeled amount of sodium phenobarbital, whereas each whole tablet of the article contained less than 90 percent of the declared amount of sodium phenobarbital.

Phenobarbital sodium tablets and *atropine sulfate tablets.* Misbranding, Section 502 (a), the statements "1000 Hypodermic Tablets" on the bottle label of the *phenobarbital sodium tablets* and "20 Hypodermic Tablets" on the tube label of the *atropine sulfate tablets* were false and misleading, since the bottles and tubes contained fewer whole tablets than the declared number.

DISPOSITION: June 21, 1948. Default decree of condemnation and destruction.

2527. Adulteration and misbranding of citrate of magnesia. U. S. v. 4 Cartons * * *. (F. D. C. No. 24593. Sample No. 18045-K.)

LIBEL FILED: April 12, 1948, Southern District of Indiana.

ALLEGED SHIPMENT: On or about February 27, 1948, by Dr. Korony Products, Inc., from Louisville, Ky.

PRODUCT: 4 cartons, each containing 36 bottles, of *citrate of magnesia* at Evansville, Ind. Examination disclosed that the product contained magnesium citrate corresponding to not more than 0.78 gram of magnesium oxide in each 100 cc.

LABEL, IN PART: "Effervescing Solution of Citrate of Magnesia U. S. P. 350 cc. 11¾ Fl. Ozs."

NATURE OF CHARGE: Adulteration, Section 501 (b), the article purported to be and was represented as "Magnesium Citrate Solution," a drug the name of which is recognized in the United States Pharmacopoeia, an official compendium, and its strength differed from the official standard since it contained in each 100 cc. an amount of magnesium citrate corresponding to less than 1.6 grams of magnesium oxide, the minimum permitted by the standard.

Misbranding, Section 502 (a), the label statement "Citrate of Magnesia U. S. P." was false and misleading as applied to an article which was not the U. S. P. product.

DISPOSITION: October 11, 1948. Default decree of forfeiture and destruction.

2528. Adulteration and misbranding of Thi-Cin Cream and Q-2 Cream and misbranding of Bloom Pills. U. S. v. 30 Jars, etc. (F. D. C. No. 24684. Sample Nos. 21160-K to 21162-K, incl.)

LIBEL FILED: On or about April 6, 1948, Western District of Missouri.

ALLEGED SHIPMENT: On or about December 2 and 4, 1947, by the Duncan Co., from Oklahoma City, Okla.

PRODUCT: 101 jars of *Thi-Cin Cream*, 91 jars of *Q-2 Cream*, and 42 bottles of *Bloom Pills* at St. Joseph, Mo. Examination showed that the *Thi-Cin Cream* was not a germicide and consisted essentially of oil of cassia and thymol in

a cold cream base; that the *Q–2 Cream* was not an antiseptic and consisted essentially of oil of cassia, thymol, and petrolatum; and that the *Bloom Pills* consisted essentially of calcium sulfide and charcoal.

NATURE OF CHARGE: *Thi-Cin Cream.* Adulteration, Section 501 (c), the strength of the article differed from that which it was represented to possess, i. e., (on label) "germicide," since the article was not a germicide. Misbranding, Section 502 (a), the label statements, "Stops that itching * * * a highly effective germicide in a wide range of skin disorders. Including, Eczema, Seborrheic dermatosis * * * Barber's Itch and externally caused Industrial dermatosis," were false and misleading, since the article was not a germicide and was not effective in the treatment of the conditions and diseases mentioned; and, Section 502 (b) (2), the article failed to bear a label containing an accurate statement of the quantity of the contents.

Q–2 Cream. Adulteration, Section 501 (c), the strength of the article differed from that which it was represented to possess, i. e., (on label) "antiseptic," since the article was not an antiseptic. Misbranding, Section 502 (a), the label statements, "For Itch * * * Kills the Itch Mite on Contact * * * for the relief of Eczema * * * externally caused acne and as an antiseptic for minor cuts and wounds," were false and misleading, since the article was not an antiseptic and was not an adequate treatment for the conditions mentioned.

Bloom Pills. Misbranding, Section 502 (a), certain statements on the label which represented and suggested that the article was effective in the treatment of acne and pimples, were false and misleading, since the article was not effective in the treatment of such conditions.

DISPOSITION: June 21, 1948. Default decree of condemnation and destruction.

2529. Adulteration and misbranding of Anademin tablets. U. S. v. 23 Boxes * * *. (F. D. C. No. 25213. Sample No. 19612–K.)

LIBEL FILED: July 26, 1948, Southern District of Ohio.

ALLEGED SHIPMENT: On or about April 21, 1948, by the Anademin Chemical Co., from Chattanooga, Tenn.

PRODUCT: 23 boxes of *Anademin tablets* at Cincinnati, Ohio. Examination showed that the potency of each tablet was equivalent to less than two-thirds of a U. S. P. digitalis unit.

LABEL, IN PART: (BOX) "100 Tablets Anademin Active Ingredients: Strophanthus .0140 mgms. (Containing .0014 mgms. of strophanthin), Squill 99.0090 mgms., Canadian Hemp (apocynum) .3260 mgms. and Elder Flowers (Sambucus) 6510 mgms., with excipients and coating. Each tablet is equivalent in potency to one U. S. P. Digitalis Unit."

NATURE OF CHARGE: Adulteration, Section 501 (c), the strength of the article differed from that which it was represented to possess, i. e., "one U. S. P. Digitalis Unit."

Misbranding, Section 502 (a), the label statement "Each tablet is equivalent in potency to one U. S. P. Digitalis Unit" was false and misleading.

DISPOSITION: September 10, 1948. Default decree of condemnation and destruction.

2530. Adulteration of Obeto. U. S. v. 5 Boxes * * *. (F. D. C. No. 25239. Sample No. 30595–K.)

LIBEL FILED: August 3, 1948, Southern District of California.

ALLEGED SHIPMENT: On or about March 10, 1948, by the Ziegler Pharmacal Co., from Buffalo, N. Y.

PRODUCT: 5 boxes, each containing 100 ampules, of *Obeto* at Roscoe, Calif. Examination showed that the product was not sterile.

LABEL, IN PART: "2 cc. plus No. 147 Obeto Chlorobutanol 0.5% (Intramuscular)."

NATURE OF CHARGE: Adulteration, Section 501 (c), the purity and quality of the article fell below that which it purported and was represented to possess, i. e., "Obeto * * * (Intramuscular)," since it was for intramuscular use and was unsterile.

DISPOSITION: August 26, 1948. Default decree of condemnation and destruction.

2531. Adulteration of Creme-A-Tone. U. S. v. 52 Bottles, etc. (F. D. C. No. 24910. Sample Nos. 2252–K to 2254–K, incl.)

LIBEL FILED: June 30, 1948, Northern District of West Virginia.

ALLEGED SHIPMENT: On or about March 15 and May 20, 1948, by Oxford Products, Inc., from Cleveland, Ohio.

PRODUCT: 52 quart bottles and 63 pint bottles of *Creme-A-Tone* at Clarksburg, W. Va. Analysis of the product (both sizes) showed that it contained an average of 2.49 percent of aluminum oxide. Analysis of the product packaged in the pint size showed that the volume of tenth-normal acid required to neutralize one gram of the gel was not more than 8.84 cc.

LABEL, IN PART: "Creme-A-Tone Aluminum Hydroxide Gel."

NATURE OF CHARGE: Adulteration, Section 501 (b), the article purported to be and was represented as "Aluminum Hydroxide Gel," a drug the name of which is recognized in the United States Pharmacopoeia, an official compendium, and its strength differed from the standard set forth in such compendium since the article, in each size, contained the equivalent of materially less than 3.6 percent aluminum oxide, whereas the compendium provides that aluminum hydroxide gel shall contain the equivalent of not less than 3.6 percent of aluminum oxide; and in the case of the article in the pint-size bottles, the volume of tenth-normal acid required to neutralize one gram of the article was less than 12.50 cc., whereas the compendium provides that the volume of tenth-normal acid required to neutralize one gram of aluminum hydroxide gel shall be not less than 12.50 cc.

DISPOSITION: September 18, 1948. Default decree of condemnation and destruction.

2532. Adulteration and misbranding of adhesive bandages. U. S. v. 480 Packages * * *. (F. D. C. No. 25260. Sample No. 28566–K.)

LIBEL FILED: August 13, 1948, District of Colorado.

ALLEGED SHIPMENT: On or about March 25, 1948, by the American White Cross Labs., Inc., from New York, N. Y.

PRODUCT: 480 packages each containing 36 *adhesive bandages* at Denver, Colo.

LABEL, IN PART: "White Cross Sterile Waterproof Adhesive Bandage."

NATURE OF CHARGE: Adulteration, Section 501 (b), the article purported to be "Adhesive Absorbent Gauze [or "Adhesive Absorbent Compress"]," a drug the name of which is recognized in the United States Pharmacopoeia, an official compendium, and its quality and purity fell below the official standard since the standard provides that adhesive absorbent gauze must be sterile and meet the requirements of the sterility tests for solids prescribed therein, whereas the article was not sterile but was contaminated with living micro-organisms.

Misbranding, Section 502 (a), the label statement "Sterile" was false and misleading.

DISPOSITION: September 28, 1948. Consent decree of condemnation and destruction.

2533. Adulteration and misbranding of prophylactics. U. S. v. 1,681 Gross * * *. (F. D. C. No. 24952. Sample No. 34250–K.)

LIBEL FILED: June 18, 1948, Northern District of California.

ALLEGED SHIPMENT: On or about December 21, 1947, and January 12, 1948, by the Duratex Corp., from Newark, N. J.

PRODUCT: 1,681 gross of *prophylactics* at San Francisco, Calif. Examination of samples showed that 4.8 percent were defective in that they contained holes.

LABEL, IN PART: "Duratex."

NATURE OF CHARGE: Adulteration, Section 501 (c), the quality of the article fell below that which it purported and was represented to possess.

Misbranding, Section 502 (a), the label statements "Prophylactics * * * for your protection * * * each piece thoroughly tested" were false and misleading as applied to an article containing holes.

DISPOSITION: September 21, 1948. Default decree of condemnation and destruction.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF FALSE AND MISLEADING CLAIMS

DRUGS FOR HUMAN USE*

2534. Alleged misbranding of Glyoxylide, Benzoquinone, and Malonide. U. S. v. Koch Laboratories, Inc., Dr. William F. Koch, and Louis Koch (2 indictments). Pleas of not guilty. Tried to a jury. No verdict rendered because of inability of jury to agree. Cases retried before second jury, but before verdict could be rendered, illness of one of twelve jurors required discharge of the jury. Case subsequently dismissed. (F. D. C. No. 6439. Sample Nos. 7694–E to 7696–E, incl., 23632–E, 23633–E, 63479–E, 72742–E, 72745–E, 73179–E, 73183–E, 79252–E, 79621–E.)

INDICTMENTS RETURNED: Between April 2 and 15, 1942, Eastern District of Michigan, against Koch Laboratories, Inc., Detroit, Mich., Dr. William F. Koch, president, and Louis Koch, secretary-treasurer.

ALLEGED SHIPMENT: On or about January 23 and February 2, 3, 4, 5, 6, and 19, 1942, from the State of Michigan into the States of California, Missouri, Kentucky, Indiana, and Oregon.

LABEL, IN PART: "Koch's Synthetic Antitoxins Glyoxylide Prepared from Aliphatic sulphonates We ascribe to it the formula OCCO Each ampoule contains approximately 2 cc. (dilution 10–12) for Allergy Cancer Infection Sold to Physicians Only"; "(Koch's Synthetic Antitoxins) * * * (1:4 Benzoquinone) Koch Each ampoule contains approximately 2 cc. aqueous solution (dilution 10–6) For the Infections and Their Sequelae Sold only to Physicians"; and "(Koch's Synthetic Antitoxins) Malonide O-c-c-c-O Each ampoule contains approximately 2 cc. aqueous solution (dilution 10–12) Anti-Alergic Sold Only to Physicians."

NATURE OF CHARGE: Misbranding, Section 502 (a), it was alleged that certain statements on the labels of the articles were false and misleading. The statements on the respective labels represented and suggested that the *Glyoxylide* was efficacious in the care, mitigation, treatment, and prevention of cancer, allergic conditions, and infection, and that it was efficacious as an antitoxin; that the *Benzoquinone* was efficacious in the cure, mitigation, treatment, and prevention of infections and sequelae of infections, and that it was efficacious as an antitoxin; and that the *Malonide* was efficacious in the cure, mitigation, treatment, and prevention of allergies, an dthat it was efficacious as an antitoxin. The indictment charged that the products would not be efficacious for those purposes.

DISPOSITION: Pleas of not guilty having been entered, the matter came on for trial before a jury on January 12, 1943. The trial continued to May 28, 1943, at which time the jury announced that it was unable to agree upon a verdict. Retrial of the matter was held, beginning February 20, 1946, and continuing to July 23, 1946. On this latter date ,the trial was ended when one of the members of the jury, then considering and deliberating upon a verdict, stated that because of illness he was unable to proceed. The Government's attorney moved the court to permit the 11 remaining jurors to continue their deliberations with a view to reaching a verdict, but because of the opposition of counsel for the defendant, the court discharged the jury. On August 17, 1948, the Government's attorney made a motion for the entry of an order of nolle prosequi, and, on the same date, the court entered an order to that effect.

2535. Misbranding of Glancaps. U. S. v. Darnell Drug Co., Wilbur F. Darnell, and George W. Darnell. Pleas of guilty. Fine of $250 against company and $10 against each individual. (F. D. C. No. 24265. Sample No. 83156–H.)

INFORMATION FILED: June 30, 1948, Southern District of Indiana, against the Darnell Drug Co., a partnership, Indianapolis, Ind., and Wilbur F. Darnell and George W. Darnell, partners in the partnership.

ALLEGED SHIPMENT: On or about July 15, 1947, from the State of Indiana into the State of Ohio.

LABEL, IN PART: "Glancaps * * * Active ingredients: Oil of Albasantal, minims 3. Oleoresin Cubeb, minims 2. Oil of Copaiba, minims 3. Rectified Oil of Terpen, minims 2. Extract of Zea Mays, grains 5. Each capsule contains 13.3 minims."

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*See also Nos. 2502–2505, 2511–2517, 2521, 2523, 2524, 2526–2529, 2532, 2533.

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements on the labels of the article were false and misleading, since they represented and suggested that the article would be an adequate treatment for enlarged prostate glands and kidney, bladder, and urinary irritations; that it would be efficacious in healing and cleansing the entire urinary system; and that it would eliminate urinary poisons. The article would not be an adequate treatment for the conditions represented; it would not be efficacious in the healing and cleansing of the entire urinary system; and it would not eliminate urinary poisons.

DISPOSITION: October 29, 1948. Pleas of guilty having been entered, the court imposed a fine of $250 against the partnership and $10 against each individual.

2536. Misbranding of National R Solution. U. S. v. 18 Bottles * * *. (F. D. C. No. 24950. Sample No. 26576-K.)

LIBEL FILED: June 14, 1948, Eastern District of Missouri.

ALLEGED SHIPMENT: On or about March 11 and May 6, 1948, by the National Drug Co., from Philadelphia, Pa.

PRODUCT: 18 4-ounce bottles of *National R. Solution* at St. Louis, Mo. Examination showed that the product consisted essentially of a solution of zinc phenolsulfonate and potassium iodide.

NATURE OF CHARGE: Misbranding, Section 502 (a), the following label statements were false and misleading, since the article would not be effective for the conditions stated and implied: (Bottle label) "Indications: For use as a mild astringent application in inflammation of mucous membranes of the urethra" and (carton label) "Indications: For use as a mild astringent application in inflammation of mucous membranes."

DISPOSITION: July 9, 1948. Default decree of condemnation and destruction.

2537. Misbranding of Mafoliata. U. S. v. 9 Bottles * * *. (F. D. C. No. 24718. Sample No. 1024-K.)

LIBEL FILED: April 16, 1948, Southern District of Florida.

ALLEGED SHIPMENT: On or about December 27, 1947, by the Mafoliata Corp., from Chicago, Ill.

PRODUCT: 9 1-quart bottles of *Mafoliata* at Coral Gables, Fla., together with a circular entitled "Ma-Ta," which was shipped with the article. Examination showed that the product consisted essentially of water, an extract of a berberine bearing drug, and a small amount of sodium benzoate.

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements in the circular were false and misleading, since they represented and suggested that the article would be effective in the treatment of syphilis, all kinds of surface infections, athlete's foot, cuts, lacerations, burns, gonorrhea, toxic poison, eczema, psoriasis, skin eruptions, stomach ulcers, gallstones, kidney stones, ulcers of the bladder and kidneys, leg ulcers, arthritis, tumor of the brain, hay fever, asthma, sinus, acne, cancer, sciatica, thrombosis, nervous disorders, dull, pasty, iron-gray or yellow jaundice complexion, aches and pains, sleepless nights, all kinds of discomforts, constipation, piles, hemorrhoids, boils, swellings, bumps, growths, abscesses in the ear drum, carbuncles, ulcers, and germ diseases and infections. The article would not be effective in the treatment of such conditions, symptoms, and diseases.

DISPOSITION: May 14, 1948. Default decree of forfeiture and destruction.

2538. Misbranding of Ball Solution. U. S. v. 216 Bottles, etc. (F. D. C. No. 24747. Sample No. 36646-K.)

LIBEL FILED: May 4, 1948, Western District of Washington.

ALLEGED SHIPMENT: On or about January 31, 1948, by the Timball Liniment Co., from Arcadia, Calif.

PRODUCT: 216 bottles of *Ball Solution* at Kirkland, Wash., together with 200 circulars entitled "The Ball Solution," which were shipped with the product. Examination showed that the product consisted essentially of alcohol, water, iodine, potassium iodide, and a small proportion of methyl salicylate.

LABEL, IN PART: (Bottle) " * * * Bone & Muscle Treatment For The Relief of Arthritis * * * For the relief of arthritis apply to the painful area * * * For sprains, swelling, and lameness * * * When applying to the knee, cover only the front, even though the pain and swelling may be in the back of the knee. Both places will be relieved * * *" and (circular)

"Bone and Muscle Treatment for Arthritis * * * once or twice a week will keep you free from the pain and crippling progress of this terrible disease. * * * Instant relief from bruised fingers * * * Sprained ankle, wrists or thumbs, stiff neck, sore muscles * * * Pain is gone instantly and swelling if any gone in the morning. * * * In cuts and bruises if applied at once. There is no chance for infection. Pain gone immediately with no bad after effects. When applied to a boil affords instant relief from pain * * * For soft corns, callouses, bunions * * * swollen * * * feet * * * this is the best treatment in the world for arthritis * * * will take the pain out of a boil and absorb it in six to eight days * * *."

NATURE OF CHARGE: Misbranding, Section 502 (a), the statements in the labeling describing the product were false and misleading, since the product would not be effective in the treatment of the conditions, diseases, and symptoms stated and implied.

DISPOSITION: June 24, 1948. Default decree of condemnation and destruction.

2539. Misbranding of Sulpho-Saline Concentrate. U. S. v. 54 Bottles * * *. (F. D. C. No. 24646. Sample No. 21192-K.)

LIBEL FILED: On or about June 1, 1948, District of Kansas.

ALLEGED SHIPMENT: On or about March 17, 1948, by the Mineral Water System of Excelsior Springs, from Excelsior Springs, Mo.

PRODUCT: 54 1-quart bottles of *Sulpho-Saline Concentrate* at Topeka, Kans. Examination showed that the product consisted essentially of a solution of salt, with small proportions of magnesium and calcium compounds.

LABEL, IN PART: "Excelsior Springs Mineral Water Sulpho-Saline Concentrate."

NATURE OF CHARGE: Misbranding, Section 502 (a), the following label statements were false and misleading, since the article was not a laxative when used in the recommended dosage, would not accomplish the benefits promised, and would not result in regular habits: "For Constipation A Natural Laxative * * * Recommended For—Constipation; helpful, dependable in the relief of loss of appetite, sick headache, bad breath, biliousness, acid indigestion, restlessness, sluggishness when caused by or associated with intestinal disturbances. Ideal Remedy—invites whole system to respond in renewed vigor and vitality * * * Directions. Follow These Simple Rules for Quick Relief. Dosage (Adults) Mix with regular water, take hot or cold. Use one tablespoonful in glass of ordinary drinking water for proper use. Two glasses, preferably hot, in morning before breakfast. Three glasses in obstinate cases of constipation. Dosage (children) Half the adult dosage is usually effective * * * Take at first signs of faulty or irregular elimination; continue until regular habits again result * * *."

DISPOSITION: June 11, 1948. The sole intervener having consented to the entry of a decree, judgment of forfeiture was entered and the product was ordered destroyed.

2540. Misbranding of Yuth. U. S. v. 58 Dozen Cartons * * *. (F. D. C. No. 24763. Sample No. 3842-K.)

LIBEL FILED: May 6, 1948, District of Maryland.

ALLEGED SHIPMENT: On or about January 27 and 29 and March 6, 1948, by Jessop Products, Inc., from New York, N. Y.

PRODUCT: 58 dozen cartons each containing 1 8-ounce bottle of *Yuth* and a circular entitled "Yuth Toiletries" and another entitled "The Story of Yuth" at Baltimore, Md. Examination showed that the product consisted of lead acetate, sulfur, pilocarpine, cantharides, glycerin, water, and perfume.

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements in the labeling of the article were false and misleading, since they represented and suggested that the article was effective to cure dandruff, seborrhea, itching scalp, falling hair, eczema, and other scalp disorders, whereas, the article was not effective for such purposes.

Further misbranding, Section 502 (e), the label of the article failed to bear the common or usual name of the active ingredients, since the statement of ingredients did not include pilocarpine, which was one of the ingredients of the article.

The article was alleged also to be misbranded under the provisions of the law applicable to cosmetics, as reported in notices of judgment on cosmetics.

DISPOSITION: June 21, 1948. Default decree of condemnation and destruction.

2541. Misbranding of Valens Ano-Perineal Support, ointment, and suppositories. U. S. v. (Dr.) George Starr White. Plea of nolo contendere. Defendant placed on probation for 4 years. (F. D. C. No. 15496. Sample No. 50318-F.)

INFORMATION FILED: April 24, 1945, Southern District of California, against (Dr.) George Starr White, Los Angeles, Calif.

ALLEGED SHIPMENT: On or about January 4, 1944, from the State of California into the State of Pennsylvania. Shipped with the drugs and device was a circular entitled "Directions for the use of Valens Ano-Perineal Support" and a booklet entitled "Points in Anatomy Physiology Hygiene."

PRODUCT: The *Valens Ano-Perineal Support* consisted of a hard, smooth ellipsoid suspended on a braided cord, with a belt to be worn about the waist. The braided cord was designed to be attached to the belt, so that the ellipsoid would be held in place. Its purpose was to support the anal region. The *ointment* consisted essentially of zinc oxide, small proportions of a bismuth compound, a sulfide, and volatile oils, in an oily base. The suppositories consisted essentially of extracts of plant drugs in a cocoa butter base.

NATURE OF CHARGE: *Valens Ano-Perineal Support.* Misbranding, Section 502 (a), certain statements in the circular and booklet were false and misleading. These statements represented and suggested that the device, when used alone or in conjunction with the *ointment* and *suppositories*, would be efficacious in the treatment and prevention of piles or itching anus, in preventing congestion in the lowest-down part of the pelvis or the ano-perineal region, in the treatment and prevention of fistulas and the form of neuritis known as "sciatica," in the treatment and prevention of severe headaches, stomach sickness, "all-gone feeling," bloating after meals or "at any time," dizziness, forgetfulness, lack of power to concentrate, itching of the skin on any part of the body, itching of the pelvic parts, itching about the anus, itching about the sexual organs, fear, melancholia, weariness after the slightest exertion, shooting pains through the abdomen as well as through the pelvis, pains in the knees and general feeling of fatigue, and the similar conditions indicated by the expression etc.; that the device, when used alone or in conjunction with the *ointment* and *suppositories*, would be efficacious in the cure, mitigation, treatment, and prevention of bleeding hemorrhoids (piles), protruding piles, blind piles (piles within the rectum), external piles, little cracks or fissures about the anus, itching about the anus or genitals, irritability about the anus or external genitals, constipation with a "dry stool," constipation with a mucous stool, partial paralysis of the lower bowel, irritability of the urinary bladder, irritability in the urethra with a "burning sensation" when urinating, frequent desire to urinate, "never-get-thru" feeling after bowel movement or after urination, "crawling sensation" about the anus, buttocks, or external genitals, pains in the pelvic nerves, especially the sciatic nerve, pains in the knees and calves of the legs, "cold sensation" in the lower limbs, especially in the feet, varicose veins in the lower limbs, sexual weakness and general feeling of being "all tired out," "crotch pains" that seem to be "deep down in the bones," and prostatic trouble in males and female troubles in women; that the device would exert a helpful and natural influence on the entire alimentary tract; that it would be an effective treatment for all troubles in the pelvis or in the sexual organs; and that tobacco smoking and nicotine are largely responsible for piles. The device, when used alone or in conjunction with the *ointment* and *suppositories*, would not be efficacious for the purposes represented and suggested; furthermore, tobacco smoking and nicotine are not largely responsible for piles.

Ointment and *suppositories.* Misbranding, Section 502 (b) (1), the products were in package form and failed to bear labels containing the name and place of business of the manufacturer, packer, or distributor; Section 502 (b) (2), the products failed to bear an accurate statement of the quantity of the contents, since the containers bore no labels containing a statement of a quantity of the contents; and, Section 502 (e), the products were not designated solely by names recognized in an official compendium and were fabricated from two or more ingredients, and they failed to bear a label containing the common or usual name of each active ingredient.

DISPOSITION: May 21, 1945. A plea of nolo contendere having been entered, imposition of sentence was suspended for 4 years and the defendant was placed on probation for that period of time.

2542. Misbranding of Dry Clime infrared lamps. U. S. v. 23 * * *. (F. D. C. No. 24711. Sample No. 30585–K.)

LIBEL FILED: April 9, 1948, Southern District of California.

ALLEGED SHIPMENT: On or about February 24 and 26, 1948, by the Dry Clime Lamp Corp., from Greensburg, Ind.

PRODUCT: 23 *Dry Clime infrared lamps* at Los Angeles, Calif., together with 250 circulars entitled "Dry Clime Lamp." Examination showed that the lamps consisted of a stand holding a reflector and an electrical heating unit.

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements in the labeling of the article were false and misleading. These statements represented and suggested that the article would bring a dry desert climate in the bedroom; that it would be effective in the treatment of acute and chronic conditions, colds, coughs, "stuffiness" or sinus headaches, infected sinuses, asthma, bronchial cough and attacks, any respiratory conditions made worse by cold, damp air and benefited by a warm, dry, desert climate, croup attacks, rheumatism, arthritis, neuritis, muscular aches and pains, acute and chronic respiratory conditions, bronchitis, and sinus conditions and sinus pains; that its use would result in easier breathing and more restful sleep; and that the article would clear the nasal passages, relieve congestion, and minimize coughing. The article would not be effective for those purposes.

DISPOSITION: July 2, 1948. The Dry Clime Lamp Corp., claimant, having consented to the entry of a decree, judgment of condemnation was entered and the product was ordered released under bond for relabeling under the supervision of the Federal Security Agency.

DRUGS FOR VETERINARY USE

2543. Misbranding of Dr. Schultz Vitalic Egg-Maker, Dr. Hisom Colic Medicine, Dr. Hisom's German Fistula Remedy, Vena-Cide Powder, and Dr. Schultz's Chick Tablets. U. S. v. Picard Pharmacy, Inc. (Venus Wholesale Co., Dr. Hisom Laboratories, and The Chlorine Chemical Co.), and Lawrence J. Doud and Ralph R. Reemts. Pleas of nolo contendere. Fine of $75 and costs against defendants jointly. (F. D. C. No. 23263. Sample Nos. 20637–H, 68541–H to 68543–H, incl., 68545–H.)

INFORMATION FILED: January 30, 1948, District of Nebraska, against Picard Pharmacy, Inc., trading under the names of the Venus Wholesale Co., Dr. Hisom Laboratories, and The Chlorine Chemical Co., at Geneva, Nebr., and against Lawrence J. Doud, president of the corporation, and Ralph R. Reemts, secretary.

ALLEGED SHIPMENT: On or about February 21, March 12 and 29, and April 7, 1947, from the State of Nebraska into the State of Kansas.

PRODUCT: Analysis disclosed that the *Dr. Schultz Vitalic Egg-Maker* consisted essentially of mineral salts containing 23.23 percent of calcium, 3.40 percent of phosphorus, 2.99 percent of iron, 9.81 percent of sodium chloride, a manganese compound, charcoal, and plant material including nux vomica and quassia; that the *Dr. Hisom Colic Medicine* consisted of an alcoholic solution containing plant extractives, with aconite indicated; that the *Dr. Hisom's German Fistula Remedy* consisted of a solution containing approximately 0.8 gm. arsenic trioxide per 100 cc.; that the *Vena-Cide Powder* consisted of a weak calcium hypochlorite; and that the *Dr. Schultz's Chick Tablets* consisted chiefly of zinc sulphocarbolate, copper sulfate, boric acid, and dextrose.

LABEL, IN PART: (Bag) "Dr. Schultz Vitalic Egg-Maker & General Conditioner * * * Dr. Schultz-Veterinary Laboratories Geneva, Nebr." or (tag) "Dr. Schultz Vitalic Egg-Maker * * * Sole Midwest Distributors Venus Wholesale Co. Geneva, Nebr."; (carton) "Dr. Hisom Colic Medicine * * * Venus Wholesale Co."; (bottle) "Dr. Hisom's German Fistula Remedy * * * Dr. Hisom Laboratories"; (can) "Vena-Cide Powder * * * The Chlorine Chemical Co."; and (can) "Dr. Schultz's Chick Tablets * * * Manufactured for The Venus Wholesale Co."

NATURE OF CHARGE: *Dr. Schultz Vitalic Egg-Maker.* Misbranding, Section 502 (a), certain statements on the label of the article, and in a circular entitled

"Dr. Schultz' Vitalic Egg-Maker" which was enclosed with the article, were false and misleading since the article would not fulfill the promises of benefit suggested and implied. The statements represented and suggested that the article was necessary for the production of eggs; that it was a medicated tonic and conditioner for poultry; that it would keep poultry in a thriving, healthy condition, and would build blood and bone; that it would be effective in producing diuresis and laxation; that it would stimulate the appetite and improve the general tone and condition of poultry; that it would be effective in checking worms and parasites in the intestinal tract of poultry and would prevent losses in poultry; that it would promote quick gains and rapid growth and would be effective in eliminating toxic poisons from clogged systems.

Dr. Hisom Colic Medicine. Misbranding, Section 502 (a), certain statements on the label of the article were false and misleading. The statements represented that the article would be efficacious in the cure, mitigation, and treatment of colic, flatulence, and bloat in horses and cattle, whereas it would not be efficacious for such purposes. Further misbranding, Section 502 (b) (2), the containers of the article bore no label containing a statement of the quantity of the contents; and, Section 502 (e) (2), the article was not designated solely by a name recognized in an official compendium and was fabricated from two or more ingredients, and its containers bore no label containing a statement of the quantity, kind, and proportion of alcohol present in the article.

Dr. Hisom's German Fistula Remedy. Misbranding, Section 502 (a), certain statements on the label of the article which represented and suggested that the article would be efficacious in the cure, mitigation, and treatment of fistulas, were false and misleading since the article would not be efficacious for such purposes; Section 502 (b) (2), the container bore no label containing a statement of the quantity of the contents; and, Section 502 (e) (2), the article was not designated solely by a name recognized in an official compendium and was fabricated from two or more ingredients, and its label failed to bear the name and the quantity and proportion of arsenic present in the article.

Vena-Cide Powder. Misbranding, Section 502 (a), certain statements on the label of the article which represented and suggested that the article would be efficacious in the cure, mitigation, treatment, and prevention of white diarrhea, cholera, and other contagious diseases of chickens, were false and misleading since the article would not be efficacious for such purposes; and, Section 502 (b) (2), the container of the article bore no label containing a statement of the quantity of the contents.

Dr. Schultz's Chick Tablets. Misbranding, Section 502 (a), certain statements on the label of the article, and in a circular entitled "1947 Price List" which was shipped prior to the shipment of the article, were false and misleading since the article would not be effective for the purposes, and would not fulfill the promises of benefit, suggested and implied. The statements represented and suggested that the article when used as directed would be capable of producing an astringent effect upon the intestinal tissue of poultry; that it would be efficacious in the cure, mitigation, and treatment of coccidiosis, fowl typhoid, fowl cholera, and white diarrhea in poultry; that it would be efficacious in the cure, mitigation, and treatment of blackhead in poultry; that it was an intestinal antiseptic; that it would relieve inflammation and would soothe the intestinal tissue; that it would disinfect drinking water; that it would help chicks through critical stages; and that when used in small doses, it would be effective to prevent diseases in poultry, and when used in large doses, it would be effective to cure diseases in poultry.

The information alleged also that the *Dr. Schultz Vitalic Egg-Maker* was misbranded under the provisions of the law applicable to foods, as reported in notices of judgment on foods.

DISPOSITION: March 10, 1948. Pleas of nolo contendere having been entered, the court imposed a fine of $75 and costs against the defendants jointly.

2544. Misbranding of Miller's Liquid Hog Medicine and Miller's Sul-Pho Tablets. U. S. v. Miller Chemical Co., Inc., and David G. Miller. Pleas of nolo contendere. Fines of $75 against corporation and $25 against individual, together with costs. (F. D. C. No. 24226. Sample Nos. 52335–H, 52337–H, 77579–H.)

INFORMATION FILED: August 5, 1948, District of Nebraska, against the Miller Chemical Co., Inc., Omaha, Nebr., and David G. Miller, president of the corporation.

ALLEGED SHIPMENT: On or about April 3 and 17 and May 5, 1947, from the State of Nebraska into the State of Minnesota.

PRODUCT: Analyses disclosed that the *Miller's Liquid Hog Medicine* consisted essentially of sodium hydroxide, sodium carbonate, sodium sulfate, camphor, anise, creosote and other phenolic compounds, potassium arsenite, and water; and that the *Miller's Sul-Pho Tablets* consisted essentially of boric acid, sodium phenolsulfonate, zinc phenolsulfonate, calcium phenolsulfonate, and copper arsenite, and was devoid of bactericidal properties when used at the recommended concentration and at 30 times the recommended concentration.

LABEL, IN PART: "Miller's Liquid Hog Medicine Concentrated," and "Miller's Sul-Pho Tablets * * * Directions As soon as birds are old enough to drink, dissolve two to four tablets in every gallon of drinking water * * *."

NATURE OF CHARGE: *Miller's Liquid Hog Medicine.* Misbranding, Section 502 (a), certain statements on the label of the article were false and misleading, since they represented and suggested that the article would be efficacious in the cure, mitigation, treatment, and prevention in hogs of intestinal infections and diarrheas associated with hyperacidity, whereas the article would not be efficacious for such purposes.

Miller's Sul-Pho Tablets. Misbranding, Section 502 (a), certain statements on the label of the article were false and misleading, since they represented and suggested that the article when used as directed would disinfect poultry drinking water and would aid in preventing the spread of diseases in poultry, whereas the article when used as directed would not accomplish the results claimed.

DISPOSITION: September 21, 1948. Pleas of nolo contendere having been entered, the court imposed a fine of $75 against the corporation and $25 against the individual, together with costs.

2545. Misbranding of Noxaton, NBX Liquid for Poultry, CWD Liquid for Poultry, Nox Inhalant Spray for Poultry, and FTC Liquid for Poultry. U. S. v. William J. Wendt (Northern States Poultry Service Co.). Plea of guilty. Fine, $450. (F. D. C. No. 24254. Sample Nos. 24422–K, 24423–K, 24425–K to 24428–K, incl.)

INFORMATION FILED: May 4, 1948, District of Minnesota, against William J. Wendt, trading as the Northern States Poultry Service Co. at Luverne, Minn.

ALLEGED SHIPMENT: From the State of Minnesota into the State of Iowa. The products were shipped between the approximate dates of May 11, 1946, and September 13, 1947, and booklets entitled "Guide to Poultry Service," leaflets entitled "Get More Eggs," and post cards entitled "Double the Aid with this Powerful Combination" were shipped on or about June 12 and August 28, 1947.

PRODUCT: Analyses disclosed that the *Noxaton* was a powdered mixture containing 7.78 percent of copper sulfate, 0.31 percent of nicotine, 0.063 percent of strychnine, and 0.02 percent of potassium iodide, ferrous sulfate, and plant matter including fragments of seeds, bark, roots, wood, leaves, resins, starch, and aromatic substances; that the *MBX Liquid for Poultry* was a dark-brown aromatic liquid containing 7.18 grams per 100 milliliters of potassium chlorate and 3.59 grams per 100 milliliters of potassium dichromate, together with small amounts of camphor, guaiacol, creosote, and eucalyptus; that the *CWD Liquid for Poultry* was a dark-brown liquid with sediment containing 0.64 percent of copper phenolsulfonate, 4.01 percent of zinc phenolsulfonate, 1.29 percent of calcium phenolsulfonate, and 1.80 percent of sodium phenolsulfonate; that the *Nox Inhalant Spray for Poultry* was a yellow, oily liquid containing mineral oil and about 50 percent of volatile oil consisting of a mixture of creosote, camphor, eucalyptus, and oil of pine; and that the *FTC Liquid for Poultry* was a greenish-blue liquid containing 1.86 percent of copper phenolsulfonate, 7.16 percent of zinc phenolsulfonate, 0.73 percent of calcium phenolsulfonate, and 1.8 percent of sodium phenolsulfonate.

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements in the labeling were false and misleading, since the articles alone or in combination with each other, as suggested in the labeling, would not be effective for the purposes claimed. The false and misleading claims in the labeling represented, suggested, and created the impression, as follows:

That the *Noxaton* would be efficacious to stimulate digestion in badly rundown poultry and would help build up and keep flocks in top-notch condition;

that it would enable turkey poults to grow faster and return greater profits to the turkey raiser; that it would be efficacious to stimulate lazy hens; that it would be efficacious in the cure, mitigation, treatment, and prevention of fowl tuberculosis; that when used in combination with "FTC Tablets," it would be efficacious in the cure, mitigation, treatment, and prevention of fowl cholera and fowl typhoid in chickens and turkeys and trichomoniasis in turkeys; that when used in combination with "Kolex," it would be efficacious in the cure, mitigation, treatment, and prevention of botulism in poultry; that when used in combination with "MBX" and "Nox Inhalant Spray," it would be efficacious in the cure, mitigation, treatment, and prevention of wet fowl pox, bronchitis, croup and colds in chickens; that when used in combination with "MBX," it would be efficacious in the cure, mitigation, treatment, and prevention of dry fowl pox in chickens, fowl pox in turkeys, and swellhead in turkeys; that it would be efficacious to restore the survivors of fowl paralysis to normal health; that the article in combination with "CWD," would be efficacious in the cure, mitigation, treatment, and prevention of intestinal type coccidiosis in chickens, blackhead in turkeys, and coccidiosis in turkeys; and that the article in combination with "MBX" and "FTC," would be efficacious in the cure, mitigation, treatment, and prevention of laryngotracheitis in chickens.

That the *MBX Liquid for Poultry* would be efficacious in the cure, mitigation, treatment, and prevention of bowel trouble in chicks; that the article in combination with "Noxaton" and "Nox Inhalant Spray" would be efficacious in the cure, mitigation, treatment, and prevention of wet fowl pox, bronchitis, roup, and colds in chickens; that the article in combination with "Noxaton," "Nox Inhalant Spray," and "FTC Tablets" would be efficacious in the cure, mitigation, treatment, and prevention of laryngotracheitis in chickens; and that in combination with "Noxaton" it would be efficacious in the cure, mitigation, treatment, and prevention of dry fowl pox in chickens, fowl pox in turkeys, and swellhead in turkeys.

That the *CWD Liquid for Poultry* in combination with "Noxaton" would be efficacious in the cure, mitigation, treatment, and prevention of intestinal-type coccidiosis in chickens and blackhead and coccidiosis in turkeys.

That the *Nox Inhalant Spray for Poultry* in combination with "Noxaton" and "MBX" would be efficacious in the cure, mitigation, treatment, and prevention of wet fowl pox, bronchitis, roup, and colds in chickens; that the article in combination with "MBX" would be efficacious in the cure, mitigation, treatment, and prevention of laryngotracheitis in chickens.

That the *FTC Liquid for Poultry* would be efficacious in the cure, mitigation, treatment, and prevention of intestinal disturbances of chickens, turkeys, ducks, and geese.

DISPOSITION: June 30, 1948. A plea of guilty having been entered, the court imposed a fine of $450.

2546. Misbranding of Dry Insecticide Dip, Guai-Calyptol, National Hog or Mange Oil, Reininger's National Yeast Feeds, Master-Mix Mineral Feed for Cattle, Reininger's National Compound for Sheep, National Hog Liquid, and Carboline. U. S. v. National Compound Co. Plea of guilty. Fine, $250. (F. D. C. No. 23267. Sample Nos. 77550–H to 77578–H, incl.)

INFORMATION FILED: February 9, 1948, District of South Dakota, against the National Compound Co., a corporation, Sioux Falls, S. Dak.

ALLEGED SHIPMENT: On or about January 27, March 27, April 3, and May 1, 1947, from the State of South Dakota into the State of Minnesota.

PRODUCT: Analyses disclosed that the *Dry Insecticide Dip* was a reddish-brown powder containing about 17.5 percent of volatile substances, chiefly naphthalene and phenols; that the *Guai-Calyptol* was an aromatic, oily, reddish-brown liquid containing 42 percent by volume of volatile oils and containing also cresylic acid, guaiacol, eucalyptol, pine oil, camphor, and eugenol, with a saponified base; and that the *National Hog or Mange Oil* was a mineral oil containing 0.146 gram of phenolic substances (calculated as phenol) per 100 milliliters; that the *Reininger's National Yeast Feeds* consisted of heterogeneous gray powder containing 9.5 percent of salt, 0.0048 percent of potassium iodide, 0.63 percent of crude fat, and 3.8 percent of crude fiber; that the *Master-Mix Mineral Feed for Cattle* was a heterogeneous cream-colored powder containing 5.76 percent of protein, 0.14 percent of crude fat, and 0.007 percent of iodine; that the *Reininger's National Compound for Sheep* was a heterogeneous reddish-

brown powder containing copper sulfate, iron sulfate, sodium sulfate, calcium carbonate, salt, iron oxide, sulfur, charcoal, areca nuts, quassia chips, aromatic oils, and plant matter; that the *National Hog Liquid* was a heterogeneous solid-liquid mixture containing 5.5 percent of copper sulfate, epsom salt, capsicum, potassium dichromate, potassium iodide, magnesium sulfate, chlorides, guaiacol, and sodium bicarbonate; and that the *Carboline* consisted essentially of a mixture of water, resins, and end products of coal-tar distillation.

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements on the labels of the products and in an accompanying circular entitled "National Yeast Feeds," which circular related to the *Reininger's National Yeast Feeds* and which was shipped prior to the shipment of such feeds, were false and misleading. These statements represented and suggested:

That the *Dry Insecticide Dip* would be efficacious in the treatment of flu in hogs; and that when used as directed about the house, barns, and hen house, it would be effective as a disinfectant;

That the *Guai-Calyptol* would be effective in the treatment of disease conditions of the respiratory tract of hogs and poultry; and that when used as a spray and as a smudge in accordance with directions, it would be capable of producing an expectorant and carminative action;

That the *National Hog or Mange Oil* possessed great healing powers for all affections of the skin, was a splendid dressing for open wounds and sores on farm animals, and would be effective in stopping and preventing coughs and as an antiseptic dressing for cuts, wounds, and sores of farm animals;

That the *Reininger's National Yeast Feeds* contained 3.4 percent of fat and not less than .035 percent of potassium iodine; that it would increase the appetite, aid digestion and assimilation, aid the stomach and other internal organs in the assimilation of the pork making elements in the usual farm feeds, eliminate practically all bowel troubles of hogs. increase the growth and egg production of chickens, give hogs bigger appetite, promote vigor and tone, and make healthier hogs and baby chicks; and that it would be effective in the cure, mitigation, and treatment of coccidiosis and other bowel troubles of chickens;

That the *Master-Mix Mineral Feed for Cattle* would be effective to stimulate the appetite, to promote digestion, and to hasten assimilation of feeds; and that it contained not less than 10 percent of crude protein, 2.5 percent of crude fat, and .08 percent of iodine;

That the *Reininger's National Compound for Sheep* would be effective in stimulating the appetite, eliminating gases, speeding digestion, adding to thrift and vigor, and expelling worms; and that it would be effective as a tonic and as a conditioner of sheep;

That the *National Hog Liquid* would be efficacious in the treatment and prevention of necrotic enteritis and infectious bowel troubles of swine; and that it contained 2 percent of copper sulfate;

That the *Carboline* would be effective in the treatment of flu in hogs.

The above statements were false and misleading, since the products would not be effective for the purposes represented; the yeast feeds contained a smaller amount of fat and potassium iodine, and the mineral feeds contained a smaller amount of crude protein, crude fat, and iodine than represented; and the hog liquid contained more than 2 percent of copper sulfate.

Further misbranding, Section 502 (b) (2), the cans containing the *National Hog or Mange Oil* and the *Carboline* bore no labels containing statements of the quantity of the contents; and, Section 502 (e) (2), the label of the *National Hog or Mange Oil* failed to bear the common and usual name of each active ingredient of the article.

The *Reininger's National Yeast Feeds* and the *Master-Mix Mineral Feed for Cattle* were alleged also to be misbranded under the provisions of the law applicable to foods, as reported in notices of judgment on foods.

DISPOSITION: April 29, 1948. A plea of guilty having been entered, the court imposed a fine of $250.

2547. Adulteration and misbranding of Young's Old Prescription. U. S. v. 25 Drums * * *. (F. D. C. No. 24740. Sample No. 18783-K.)

LIBEL FILED: April 23, 1948, Northern District of Ohio.

ALLEGED SHIPMENT: On or about January 21, 1948, by Young's Stock Food Co., from Roaring Spring, Pa.

PRODUCT: 25 125-pound drums of *Young's Old Prescription* at New Philadelphia, Ohio. Analysis showed that the product contained 2.98 percent of protein, 0.83 percent of fat, 3.35 percent of crude fiber, 18.12 percent of calcium, 42.32 percent of phosphoric acid, 2.20 percent of iron, 0.003 percent of iodine, and 0.0017 percent of strychnine, with small amounts of copper and manganese, and possibly the other ingredients declared on the label.

LABEL, IN PART: "Analysis Protein 3:55 Fat 1:25 Fiber 3:87, Mineral Analysis Calcium 18:42 Phos. Acid 26:63. Trace Minerals Manganese, Iodine (Stabilized). Copper, Iron, Cobalt Vitamin D_2 For Four-Footed Animals Guaranteed to contain 16,000 U. S. P. Units per Pound. Ingredients: DiCalcium Phosphate, Iron Oxide, Poke Root, Fenugreek Seed, Licorice Root, Star Anise Seed, Cocoa Meal, Nux Vomica, Trace Mineral Compound (Iron, Iodine, Manganese, Copper, Cobalt), Vitamin D_2 Compound (Irradiated Ergosterol)."

NATURE OF CHARGE: Adulteration, Section 501 (c), the quality and strength of the article differed from that which it was represented to possess, since it contained less protein and fat and more phosphoric acid than declared on the label.

Misbranding, Section 502 (a), certain statements in the leaflet contained in each drum were false and misleading, since they represented and suggested that the article when used as directed would be effective in the treatment of scours in calves and as a general tonic for cows and bulls, whereas the article would not be effective for such purposes; and, Section 502 (e) (2), the article was fabricated from two or more ingredients, and its label failed to bear a statement of the quantity or proportion of strychnine contained therein.

DISPOSITION: May 18, 1948. The Young's Stock Food Co., claimant, having admitted the facts set forth in the libel, judgment of condemnation was entered and the product was ordered released under bond for reprocessing and relabeling under the supervision of the Food and Drug Administration.

2548. Adulteration and misbranding of Chexit. U. S. v. 47 Bottles, etc. (F. D. C. No. 24881. Sample Nos. 25368–K, 25369–K.)

LIBEL FILED: June 10, 1948, District of South Dakota.

ALLEGED SHIPMENT: On or about April 16, 1948, by the United Farmers Exchange, from Council Bluffs, Iowa.

PRODUCT: 47 1-pound size bottles and 12 3-pound size bottles of *Chexit* at Howard, S. Dak. Analyses showed that the product consisted chiefly of calcium carbonate, powdered nux vomica, poke root, ginger, fenugreek, and potassium iodide. The proportion of potassium iodide contained in the product in the 1-pound size bottles was 0.032 percent.

NATURE OF CHARGE: Adulteration, Section 501 (c), the strength of the article in the 1-pound size bottles differed from that which it purported and was represented to possess, namely, "Potassium iodide, .40%."

Misbranding, Section 502 (a), the name "Chexit" and certain statements on the label of the article were false and misleading. The name and the statements on the label of the article in the 1-pound size represented and suggested that the article when used as directed was effective to check disease conditions of the bowels and stomach of animals; that it was a demulcent tonic and a tonic to the appetite of animals; and that it contained 0.40 percent of potassium iodide. The article when used as directed was not effective for the purposes represented; it was not a tonic as represented; and it did not contain 0.40 percent of potassium iodide. The name of the article and the statements on the label of the 3-pound size of the article represented and suggested that the article when used as directed was effective to check disease conditions of calves, lambs, colts, kids, sows with suckling pigs, milch cows, and steers; and that it was a demulcent tonic and a tonic to the appetite of animals. The article when used as directed was not effective for the purposes represented, and it was not a tonic as represented.

DISPOSITION: July 27, 1948. Default decree of condemnation and destruction.

2549. Misbranding of Spear Chick-Tabs, Spear Tonic, and Spear Quit-Pick. U. S. v. 26 Bottles, etc. (F. D. C. No. 24713. Sample Nos. 20877–K, 20882–K, 20883–K.)

LIBEL FILED: On or about April 13, 1948, Western District of Missouri.

ALLEGED SHIPMENT: The *Spear Chick-Tabs* were shipped from Cedar Rapids, Iowa, by Barlow, Wright & Shores, Inc., on or about March 1, 1947, and the other products were shipped by the Corn King Co. (successor to Barlow, Wright & Shores, Inc.), from Cedar Rapids, Iowa, on or about November 12, 1947, and February 9, 1948.

PRODUCT: 26 100-tablet bottles of *Spear Chick-Tabs*, 7 1-pound packages and 1 4-pound package of *Spear Tonic*, and 105 jars of *Spear Quit-Pick* at Kansas City, Mo.

LABEL, IN PART: "Spear Chick-Tabs Active Ingredients: Ammonium, Zinc, Iron and Copper Phenolsulfonate. Inert Ingredients: Boric Acid. 20 Grains Each" and "Spear Tonic Nux Vomica (.36 grain Strychnine per lb.), Quassia, Sulphur 1.35%, Mustard, Iron Sulphate, Sodium Carbonate, Capsicum 2% Oyster Shell Flour (Calcium Carbonate) 34%, Sodium Chloride (Salt) ½ of 1%, Charcoal 15%, Oxide of Iron."

NATURE OF CHARGE: *Spear Chick-Tabs.* Misbranding, Section 502 (a), the following label statements were false and misleading, since the article was not effective as an astringent medication, as an astringent, or of any value in the treatment of diarrhea conditions of chickens and turkeys: "An astringent medication to be used in the drinking water for Poultry and Turkeys * * * An Effective Astringent Spear Chick-Tabs are of especial value in the aid of simple diarrhea not caused by infection, in Chickens and Turkeys of all ages. As an Astringent For Baby Chicks and Poults * * * For Pullets and Turkeys * * * For Adult Birds * * *."

Spear Tonic. Misbranding, Section 502 (a), the following label statements were false and misleading, since the article was not effective as a tonic, as a conditioning tonic, as an appetizer, and as an aid in the assimilation of the food of poultry, turkeys, ducks and geese, and was not effective to pep birds up after worming and to build appetite and vitality: "Tonic * * * A Conditioning Tonic and Appetizer for Poultry, Turkeys, Ducks and Geese * * * Spear Tonic peps birds up after worming, builds appetite and vitality * * * will aid in assimilation of the food * * * An Effective Tonic, Appetizer and Conditioner."

Spear Quit-Pick. Misbranding, Section 502 (e) (2), the article was fabricated from two or more ingredients, and its label failed to bear the common or usual name of each active ingredient.

DISPOSITION: July 7, 1948. The sole intervener having consented to the entry of a decree, judgment of condemnation was entered and the products were ordered destroyed.

DRUG ACTIONABLE BECAUSE OF DECEPTIVE PACKAGING

2550. Misbranding of Cocilana Cough-Nips (cough drops). U. S. v. 57 Boxes * * *. (F. D. C. No. 24330. Sample No. 8259–K.)

LIBEL FILED: February 5, 1948, District of New Jersey.

ALLEGED SHIPMENT: On or about November 18, 1947, by Cocilana, Inc., from Brooklyn, N. Y.

PRODUCT: 57 boxes, each containing 40 packages, of *Cocilana Cough-Nips* (cough drops) at Newark, N. J.

LABEL, IN PART: (Package) "Cocilana Cough-Nips Original Medicated Net Weight 1 1/16 Ounces."

NATURE OF CHARGE: Misbranding, Section 502 (i) (1), the container of the article was so filled as to be misleading, since an additional fifteen cough drops could be placed in each package.

DISPOSITION: March 22, 1948. Default decree of condemnation. The product was ordered delivered to charitable institutions.

INDEX TO NOTICES OF JUDGMENT D. D. N. J. NOS. 2501 TO 2550

PRODUCTS

[1] (2534) Prosecution contested. Tried to a jury.

SHIPPERS, MANUFACTURERS, AND DISTRIBUTORS

[1] (2534) Prosecution contested. Tried to a jury.

U. S. GOVERNMENT PRINTING OFFICE: 1949

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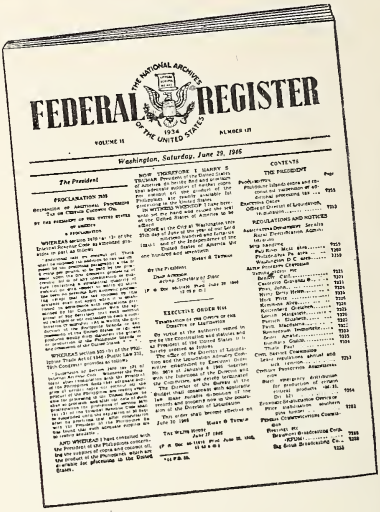

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NOTICES OF JUDGMENT UNDER THE FEDERAL FOOD, DRUG, AND COSMETIC ACT

[Given pursuant to section 705 of the Food, Drug, and Cosmetic Act]

2551–2600

DRUGS AND DEVICES

The cases reported herewith were instituted in the United States district courts by the United States attorneys acting upon reports submitted by direction of the Federal Security Administrator.

OSCAR R. EWING, *Administrator, Federal Security Agency.*

WASHINGTON, D. C., *June 16, 1949.*

CONTENTS*

*For omission of, or unsatisfactory, ingredients statements, see Nos. 2591, 2596; failure to bear a label containing an accurate statement of the quantity of the contents, No. 2596; cosmetic, actionable under the drug provisions of the Act, No. 2583 (Frenco's Papaya Tooth Powder).

835002—49——1

DEVICE ACTIONABLE BECAUSE OF POTENTIAL DANGER WHEN USED ACCORDING TO DIRECTIONS

2551. Misbranding of Gomco ring pessaries. U. S. v. 6 Devices, etc. (F. D. C. No. 25549. Sample No. 29003–K.)

LIBEL FILED: September 9, 1948, District of Colorado.

ALLEGED SHIPMENT: On or about August 17, 1948, from Buffalo, N. Y., by the Gomco Surgical Mfg. Corp.

PRODUCT: 6 *Gomco ring pessary devices* at Denver, Colo., together with 6 circulars entitled "Technique For The Use Of The Gomco Intrauterine Silver Ring Pessary." Examination showed that the device was a metallic ring, approximately one inch in diameter, which was fashioned from a spring, the coils of which were approximately $\frac{3}{32}$ inch in diameter.

NATURE OF CHARGE: Misbranding, Section 502 (j), the article was dangerous to health when used with the frequency and duration recommended and suggested in its labeling, namely, "Patient lies in the Gynecological position on the examination table. The Speculum is inserted and antiseptic wet swabs are applied to the Os in order to remove any mucous. The Tenaculum Forceps used to seize the anterior lip is held in the left hand to steady the cervix and bend it down. A Sound is introduced in order to establish the position, size and direction of the Uterine Cavity and also to determine the caliber of the cervical canal. The Speculum is then pressed posteriorily. It is most important to establish the length of the uterine cavity as the ring must be placed so as to be in contact with the upper end of the cavity. The bend in the cervical canal is straightened by pulling gently on the Tenaculum. Occasionally projecting folds in the mucous membrane of the cervical canal (especially in hypo-plastic uteri) causes some difficulty. This can be overcome by dilating the cervical canal with a Hegar's Dilator so that the introducing instrument can be passed after the dilation. This is quite easy if a No. 6 dilator can be passed. If No. 5 goes in easy it is not necessary to try No. 6 as this is wide enough for the introducing instrument. The latter is pushed in until the resistance of the fundus uteri is encountered. The ring which is compressible adapts itself to the canal while passing through it and resumes its circular shape when it gets into the uterine cavity. You can see this from an X-ray plate of the ring in situ. On withdrawing the introducing instrument, the walls of the uterus at the internal os detach the ring from the instrument and the latter comes out easily, leaving the ring behind. The Tenaculum Forceps are then removed, any blood clots are swabbed up, the Speculum is removed and a swab left on the vaginal entrance. * * * Care must be taken that the lower pole of the ring is within the cavity. * * * The ring may be left in for at least one year."

DISPOSITION: October 29, 1948. The Gomco Surgical Manufacturing Corp. having executed an acceptance of service and authorization for taking of final decree, judgment of condemnation and destruction was entered.

DRUG REQUIRING CERTIFICATE OR RELEASE, FOR WHICH NONE HAD BEEN ISSUED

2552. Misbranding of penicillin-G sodium crystalline. U. S. v. 88 Vials * * *. (F. D. C. No. 25508. Sample No. 9439–K.)

LIBEL FILED: September 1, 1948, Southern District of New York.

ALLEGED SHIPMENT: On or about March 8, 1948, from Newark, N. J., by the Vitamin Corporation of America.

PRODUCT: 88 100,000-unit vials of *penicillin-G sodium crystalline* at New York, N. Y.

LABEL, IN PART: "Penicillin-G Sodium Crystalline * * * Manufactured for Solvecillin, Inc. * * * Newark, New Jersey."

NATURE OF CHARGE: Misbranding, Section 502 (1), the article was represented as a drug composed wholly of penicillin-G sodium crystalline, a derivative of a kind of penicillin, and it was not from a batch with respect to which a certificate or release had been issued as provided for by Section 507; and, Section 502 (a), the label statement "Lot No. 3127C Exp. Date Nov. 1950" was false and misleading since the statement represented and suggested that the article had been certified by the Federal Security Administrator under such identifying terms, whereas, it had not been so certified.

DISPOSITION: September 23, 1948. Default decree of condemnation. The product was ordered delivered to a charitable organization.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF FAILURE TO BEAR ADEQUATE DIRECTIONS OR WARNING STATEMENTS*

2553. Action to enjoin and restrain the interstate shipment of Paracelsus. U. S. v. American Biochemical Corporation. Injunction granted. (Inj. No. 203.)

COMPLAINT FILED: On or about November 18, 1948, Northern District of Ohio, against the American Biochemical Corp., Cleveland, Ohio.

ALLEGED VIOLATION: The complaint alleged that the defendant had been and was continuing to ship in interstate commerce a product known as *Paracelsus*, which consisted essentially of a mixture of chemical salts and which was distributed for use both as a dietary food supplement and for therapeutic purposes.

That accompanying the product there was and had been theretofore printed and graphic matter relating to the product entitled "Malnutrition, Disease, Due to Mineral Lack," which described the product and related to it; that the printed and graphic matter had been shipped by the defendant into interstate commerce and had been used with the product by the consignees and had been associated together with the product.

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements in the accompanying labeling were false and misleading. These statements represented and suggested that the article was effective to prevent and cure malnutrition and disease, to provide pep, to stimulate hormone production, and to prevent and cure arthritis; and that all individuals suffer from mineral deficiency and would benefit by use of the article. The article was not effective for such purposes and was not capable of fulfilling the promises of benefit

*See also No. 2596.

stated and implied. Further misbranding, Section 502 (a), the following label statements were false and misleading since if taken as directed, the article would supply materially less calcium and iron than stated:

When Taken According to Directions Will Supply Percentage of Daily Requirements as Listed

	Calcium	*Iron*
Man	13.50%	16.00%
Woman	13.50%	16.00%
Pregnancy latter half	7.00%	12.75%
Lactation	5.25%	12.75%
Children 1 to 9 years	10.75%	19.20%
Children 10 to 12 years	9.00%	16.00%
Girls 13 to 15 years	8.00%	13.00%
Boys 12 to 15 years	7.50%	13.00%
Girls 16 to 20 years	10.50%	13.00%
Boys 16 to 20 years	7.50%	13.00%

Further misbranding, Section 502 (f) (1), the article failed to bear adequate directions for use since at times it failed to bear labeling which set forth the purposes for which the article was intended to be used as a drug.

The article was alleged also to be adulterated and misbranded under the provisions of the law applicable to foods, as reported in notices of judgment on foods.

PRAYER OF COMPLAINT: That the defendant be restrained and enjoined during the pendency of the action and permanently, from shipping in interstate commerce an article known as *Paracelsus*, or under any other name, which was adulterated or misbranded as alleged.

DISPOSITION: December 10, 1948. The defendant having consented to the entry of a decree, a permanent injunction was granted enjoining and restraining the defendant from shipping in interstate commerce an article under the trade name *Paracelsus*, or under any other name, which was adulterated or misbranded as alleged in the complaint.

2554. Misbranding of Mel-O-Eze, Mount Clemens Mineral Salts, Mount Clemens Cleme-Tone Concentrated Mineral Water, and Pile-Dume. U. S. v. 42 Jars, etc. (F. D. C. No. 24919. Sample Nos. 14868-K to 14871-K.)

LIBEL FILED: July 6, 1948, Northern District of Illinois.

ALLEGED SHIPMENT: On or about May 10, 1948, from Mount Clemens, Mich., by the Mount Clemens Mineral Water Co., Inc.

PRODUCT: 42 1-ounce jars of *Mel-O-Eze*, 24 75-pound drums of *Mount Clemens Mineral Salts*, 36 6-ounce bottles of *Mount Clemens Cleme-Tone Concentrated Mineral Water*, and 42 1-ounce jars of *Pile-Dume* at Chicago, Ill. Examination showed that the *Mel-O-Eze* consisted essentially of chloride and carbonates of potassium, sodium, calcium, and magnesium in a fatty ointment base; that the *Mount Clemens Mineral Salts* consisted essentially of water and chlorides of calcium, magnesium, sodium, and a small proportion of iron; that the *Mount Clemens Cleme-Tone Concentrated Mineral Water* consisted essentially of water and calcium and magnesium and sodium chlorides; and that

the *Pile-Dume* consisted essentially of the chlorides and carbonates of sodium, potassium, calcium, and magnesium in a fatty base containing some water.

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements on the labels of the articles were false and misleading. The statements represented and suggested that the *Mel-O-Eze* would be effective in the treatment of athlete's foot and eczema; that the *Mount Clemens Mineral Salts* would be effective in the treatment of rheumatism, nervousness, neuritis, and arthritis, and for the relief of that tired, weary, run-down feeling and body fatigue; that the *Mount Clemens Cleme-Tone Concentrated Mineral Water* would be effective in the treatment of gastric hyperacidity and ulcerated stomach; and that the *Pile-Dume* would be effective in the treatment of bleeding and protruding piles. The articles would not be effective for such conditions.

Further misbranding, Section 502 (f) (2), the labeling of the *Pile-Dume* failed to bear such adequate warnings against use in those pathological conditions where its use may be dangerous to health, in such manner and form as are necessary for the protection of users, since its labeling failed to warn that bleeding may be an indication of cancer.

DISPOSITION: January 13, 1949. The Mount Clemens Mineral Water Co., Mount Clemens, Mich., claimant, having consented to the entry of a decree, judgment of condemnation was entered and the product was ordered released under bond for relabeling, under the supervision of the Federal Security Agency.

2555. Misbranding of Tox Eliminator devices. U. S. v. 2 * * *. Tried to the court. Verdict for the Government. Decree of condemnation and destruction. (F. D. C. No. 24752. Sample Nos. 68180-H, 68181-H.)

LIBEL FILED: May 10, 1948, Eastern District of Oklahoma; amended libel filed July 9, 1948.

ALLEGED SHIPMENT: On or about December 2 and 26, 1946, by the Tox Eliminator Co., from Glendale, Calif., and Louisville, Ky.

PRODUCT: 2 devices known as *Tox Eliminator* at Poteau, Okla. The device was an apparatus for flushing the colon.

NATURE OF CHARGE: Misbranding Section 502 (a), certain statements in the accompanying labeling of the device, consisting of circular letters dated January 1, 1947, addressed to "Dear friend" and leaflets entitled "The Modern, Scientific Drugless Way to Health" and "The Magic Power of Water," were false and misleading. These statements represented and suggested that the device was effective in helping to purify the blood stream in performing its marvelous function of healing and correcting in all parts of the body; in treating intestinal toxemia, arthritis, rheumatism, neuritis, high and low blood pressure, toxic heart conditions, ulcers of stomach and bowels, colitis, chronic appendicitis, gall bladder and liver troubles, kidney and bladder troubles, asthma, migraine, toxic skin troubles, lumbago, excessive fatigue, foul breath, indigestion, irregular heart, menopause disturbances, muddy or pimply complexion, nervousness, pruritus, sinus trouble, run-down condition, shortness of breath, sleeplessness, ulcers of the colon, and disturbed bowel conditions; in giving necessary tone to the tissues; in cleansing the blood stream by assisting in eliminating the causes of blood pollution; in assisting in relieving sinus and antrum complications; helping to re-establish a normal peristalsis or natural muscular activity of the intestines; in helping improve the complexion by assisting in eliminating the causes of pollution of the blood stream; in helping to prevent hardening of the arteries by minimizing the

deposits of calcium and magnesium salts on arterial walls; in assisting in a more rapid recovery from a major surgical operation; in removing at their source disease-producing materials not properly discharged by the liver, colon, and kidneys, and as a result carried by the blood and lymph stream to every part of the body, tissues, joints, sinus, appendix, gall bladder and so on, thereby helping the body to stop further damage and helping nature rebuild the affected parts and restore them to normal; in removing causes of irritation and numerous infections; in treating acute and chronic disorders; in helping to determine the cause of a great many gastrointestinal disorders; and in treating female disorders, prostatic disorders, rectal diseases, sciatica, heart involvements, and many other pathological conditions too numerous to mention. The device was not effective for such purposes.

It was alleged also in the libel that if it should be determined that the leaflets and circular letters did not accompany the device, the device was misbranded under Section 502 (f) (1), in that its labeling failed to bear adequate directions for use since the labeling failed to state any diseases or conditions for which the device was intended to be used; and, further, in that its labeling failed to bear adequate directions for use in the aforesaid diseases, symptoms, and conditions for which the device was intended to be used and for which it was recommended and suggested in its advertising, disseminated and sponsored by and on behalf of the manufacturer and distributor.

DISPOSITION: J. C. Rabourn and Ada Rabourn, claimants, having filed an answer denying the material allegations of the libel, the case came on for trial before the court on November 16, 1948. The trial was concluded on the same day, and the case was taken under advisement by the court. On February 14, 1949, the court handed down the following findings of fact and conclusions of law:

BROADDUS, *District Judge:*

FINDINGS OF FACT AND CONCLUSIONS OF LAW

"1. The United States brings this action on libel of information for confiscation of two devices manufactured and sold for use as colonic irrigators, under the name of Tox Eliminator. The devices were shipped in interstate commerce from the manufacturer, Tox Eliminator Company in Glendale, California, to the claimants, Dr. J. C. Rabourn and Dr. Ada Rabourn, in Poteau, Oklahoma, within the Eastern District of Oklahoma, where the devices were seized. The articles are alleged to have been misbranded within the provisions of section 301 of the Federal Food, Drug, and Cosmetic Act (21 U. S. C. A. 331). This court has jurisdiction. 21 U. S. C. A. 334; 28 U. S. C. A. Sept. 1, 1948) sec. 1356.

"2. The Tox Eliminator is a device consisting of certain pipes, tubes, faucets and accessories offered for sale and sold to be used as a colonic irrigator and providing for controlled irrigation of the colon by water. The device was manufactured and sold by the Tox Eliminator Company of Glendale, California. The agent of the company in Oklahoma was one Mr. Fred McCabe.

"3. The company had forwarded by mail from Glendale to McCabe in Oklahoma two pamphlets entitled 'The Magic Power of Water' and 'The Modern Scientific Drugless Way to Health,' and a letter to be used as a circular letter, addressed to 'My dear friend.' These pamphlets advertising the Tox Eliminator contained representations as to its curative power. McCabe made a sale of one of the devices to a doctor in Sulphur shortly before the sale of the Tox Eliminators here considered. Using the original pamphlets

and letter that he had received from California he had identical printed copies thereof made in Shawnee, the only change being the name of the doctor, and these were used and distributed in connection with the Sulphur sale.

"4. Two of the devices were sold by McCabe in September of 1946 to the Rabourns, the claimants in this case. The devices were thereafter shipped in interstate commerce from Louisville, Kentucky, to which city they had been shipped from Glendale, California, and stored, to Poteau, Oklahoma, in December of 1946 and delivered to the Rabourns. At the time of the sale it was agreed as a part of the contract of sale that McCabe would conduct a scheme of advertisement and promotion of the devices by causing the pamphlets and letters, in the form furnished to McCabe by the company and heretofore identified, to be mailed to a list of prospective patients in the vicinity of Poteau, Oklahoma, to induce them to seek treatments by the use of the devices in the office of the claimants. The literature was examined by the Rabourns and, upon their approval, copies of the pamphlets and the circular letter received by McCabe from the company in Glendale, or copies of the former Shawnee printing of the same literature were reproduced or printed in Shawnee and mailed by a local mailing agency to some two thousand persons of a prepared list of prospective patients. The Rabourns reimbursed McCabe for this expense as agreed in the sales contract.

"5. The literature mailed made claims as to the effectiveness of the machine in the cure or relief of many of the ills that affect the human body. Though it is admitted by the claimants that these claims are false, they assert that the government may not successfully proceed in this libel of information because the literature in question under the facts was not a labeling of the devices as it was not (1) upon the device sold and shipped in interstate commerce or (2) did not accompany such device within the meaning of the Federal Food, Drug and Cosmetic Act (21 U. S. C. A. Sec. 321 et seq.).

"A. The Federal Food, Drug and Cosmetic Act (21 U. S. C. A. Sec. 321, et seq.) is primarily for the protection of the public and should receive a liberal construction. United States v. Dotterweich, 320 U. S. 277; Pasadena Research Laboratories, Inc. v. United States, 9 Cir., 169 F. 2d 375; Arner Co. v. United States, 1 Cir., 142 F. 2d 730; United States v. Research Laboratories, 9 Cir., 126 F. 2d 42.

"B. As the literature used makes false claims of the curative value and effectiveness of the device, it is a misbranding if such literature be considered to be a part of the labeling under the provisions of the statute. 21 U. S. C. A., Sec. 352 (a); United States v. One Device, 10 Cir., 160 F. 2d 194. 'Labeling' means all labels and other written, printed or graphic matter upon any article or its container or wrapper; or accompanying such article. 21 U. S. C. A. Sec. 321 (m). The circular and pamphlets not being upon or attached to the devices or their containers or wrappers, the inquiry is whether such matter accompanied the devices within the purview of the section. The phrase 'accompanying such article' is not restricted to 'labeling' that is on the article of package forwarded in interstate commerce. As used in the Act, 'accompanying' described the relationship between the article and its labeling. The accompaniment is one of commercial association. An article or device is accompanied by labeling when the labeling supplements or explains the use of the article. Kordel v. United States (not officially reported) No. 30, October Term, Nov. 22, 1948, United State v. Kordel, 7 Cir., 164 F. 2d 913; United States v. Kordel, D. C. N. D. Ill., 66 F Supp. 538; United States v. Lee, 7 Cir.,

131 F. 2d 464; United States v. Paddock, D. C. W. D. Mo., 68 F. Supp. 407; United States v. 7 Jugs, etc., D. C. Minn. 53 F. Supp. 746.

"Here both the literature and the device originated in California, the device being shipped in interstate commerce and the original or copy of the literature being sent from California to Oklahoma by mail to be subsequently used as the pattern or copy for the pamphlets and circulars sent out pursuant to the sales agreement. It was 'an accompanying' within the meaning of the Act. To hold otherwise would be to permit an escape from purpose of the Act by the plainest sort of subterfuge.

"C. Nor does the fact that the literature was distributed for advertising purposes prevent it from being 'labeling' as defined by the Act. U. S. v. Kordel, 7 Cir., supra; United States v. Paddock, D. C. W. D. Mo., 67 F. Supp. 819.

"6. The only labels attached to the devices are the respective name plates, each with the words 'Tox Eliminator, Tox Eliminator Company, Inc., Glendale, California, Serial No. ——.' The government contends that should the circulars be held not to be labeling within the concept of the Federal Food, Drug and Cosmetic Act then the devices are misbranded because of the insufficiency of the labeling.

"7. As a part of the sales agreement it was agreed that soon after the delivery of the machines the company would conduct a clinic called a 'health clinic' to introduce the machines to the public. A licensed chiropractor of California, not licensed to practice the healing art in Oklahoma, was sent from California office of the Tox Eliminator Company to demonstrate the device and assist in the holding of the clinic. He gave a short course of instruction to the Rabourns so they might understand the operation of the devices and he assisted in the giving of treatments with the devices. Following this clinic and instruction, like treatments were given under the supervision of either of the Rabourns in their offices.

"D. A device shall be deemed to be misbranded unless its labeling bears adequate directions for use provided where such requirement as applied to such device is not necessary for the protection of the public health the Administrator shall promulgate regulations exempting such device from the requirement. 21 U. S. C. A. Sec. 352 (f) (1).

"E. The Federal Security Administrator is authorized to promulgate regulations for the efficient enforcement of the law (21 U. S. C. A. Sec. 371 (a)); and such regulations may be interpretive of the statute in so far as they do not conflict with or add to the provisions of the law. United States v. Antikamnia Chemical Co., 231 U. S. 654; 666; Arner v. U. S., 1 Cir., 142 F. 2d 730, certiorari denied 323 U. S. 730. Under such authority the Administrator has adopted regulations not inconsistent with his powers providing that directions for use may be inadequate by reason of omission in whole or in part of incorrect specifications of directions for use in all conditions for which devices are prescribed, recommended or suggested in the labeling or advertising disseminated or sponsored by its manufacturer or packer, or in such other conditions as said device is commonly or effectively used. 21 Code of Federal Regulations, Cum. Supp., Sec. 2.106 (a) (1). The label on the device containing the words 'Tox Eliminator' standing alone is not a misbranding as the device tends to remove toxins (U. S. v. One Device, supra) but in the light of Regulations Sec. 2.106 (a) (1) the branding is inadequate because the words on the devices do not include all the claims for the curing or treatment set out in the advertising circulars. United States v. 150 Packages

Bush Mulso Tablets, Civil No. 4415, D. C. E. D. Mo. (not officially reported); United States v. 516 Cases Nue-Ovo, D. C. S. D. Cal. No. 7418-C, 1948 (not officially reported). The devices were misbranded unless exempted by some other provision of the law or regulations made pursuant thereto.

"8. As to many of the diseases and conditions referred to in the circulars the devices are of no benefit as a cure and afford no relief. To such an extent the claims and implications of the circulars are false and misleading.

"F. Exempted from the requirement of Sec. 352 (f) (1) of the statute (except as otherwise provided by paragraph (h) and (i) of Sec. 2.106 of the regulation) is the delivery or shipment of a device complying with certain conditions, among which conditions are that adequate information for the use of the device by a physician is readily available (Code of Federal Regulations, Supp. 1944, Sec. 2.106 (b) (5) (i)); and that the shipment or delivery complies with all the conditions set forth in paragraphs (b) (3) of such regulatory section and is made to a physician to be dispensed by or under the direction of a physician in his professional practice (Code of Federal Regulations, Supp. 1944, Sec. 2.106 (e)). The effect of the regulation in application to the facts of this case is that the shipment or delivery of the device is exempted from Sec. 352 (f) (1) of the statute if adequate information for the use of the device by a physician is readily available; and it is made to a physician to be dispensed by or under the direction of a physician. That the devices were delivered to physicians to be dispensed under the direction of such physicians is clear. There remains the question of whether adequate information for the use of the device by a physician is readily available. The adequate information required relates to the use of the machine in the treatment of the diseases and conditions for which it is intended to be used, as set forth in the circulars. Such adequate information must be readily available. While it may be possible that harm or injury might not result in certain instances from use of the devices under the supervision of chiropractors, the exemption from the requirement of the statute may not be allowed for that reason standing alone. It is within the spirit and intent of the statute that the public be protected from fraudulent representations of the curative or beneficial result to be secured from the use of a device; and the words in the exemption of the regulation that 'adequate information for the use of the device by a physician be readily available' embraces the concept of truthful and adequate information of its use to bring about probable cure of or some relief from the diseases and conditions contained in the circulars and advertisements. As many of the claims of the circulars have no basis in fact, adequate information for their use may not be considered as readily available. Were it otherwise the probable harm from the use of the devices for conditions or diseases or the delay in securing relief by other means might find justification never contemplated but intended to be denied by the broad purposes of the statute.

"Judgment of condemnation will be entered as of the date of the filing of these findings of fact and conclusions of law, this the 14th day of February, 1949, and the machines will be delivered to the proper authorities for disposition as provided by law."

In accordance with the foregoing findings of fact and conclusions of law, judgment of condemnation was entered as of February 14, 1949, and the devices were ordered destroyed.

835002—49——2

2556. Misbranding of Cloro devices. U. S. v. 5 * * *. F. D. C. No. 23629. Sample Nos. 82720–H, 82721–H.)

LIBEL FILED: August 14, 1947, District of Montana.

ALLEGED SHIPMENT: On or about April 23 and May 7, 1947, by the L. P. Dickey Co., from Tucson, Ariz.

PRODUCT: 5 *Cloro* devices at Butte, Mont. Examination showed that the devices were electrical, and that when charged and operated in accordance with the directions furnished, they would give off chlorine gas and vapors of eucalpytol.

LABEL, IN PART: "Cloro Reg." and "Roh Company Tucson Arizona."

NATURE OF CHARGE: Misbranding, Section 502 (f) (1), the labeling of the devices failed to bear adequate directions for use.

DISPOSITION: October 13, 1947. Default decree of condemnation. It was ordered that the devices be turned over to the Montana State School of Mines, to be disassembled and the component units thereof to be used for scientific and experimental purposes.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF DEVIATION FROM OFFICIAL OR OWN STANDARDS*

2557. Adulteration of dextrose in distilled water. U. S. v. 28 Bottles * * *. (F. D. C. No. 25391. Sample No. 6387–K.)

LIBEL FILED: August 17, 1948, Western District of Pennsylvania.

ALLEGED SHIPMENT: On or about March 17 and May 12, 1947, from Cleveland, Ohio.

PRODUCT: 28 bottles of *dextrose in distilled water* at Pittsburgh, Pa. The product was in hermetically sealed flasks and was intended for intravenous injection.

NATURE OF CHARGE: The article was adulterated while held for sale after shipment in interstate commerce under Section 501 (b), in that it purported to be and was represented as "Dextrose Injection," a drug the name of which is recognized in the United States Pharmacopoeia, an official compendium, and the quality and purity of the article fell below the official standard since it was contaminated with undissolved material.

DISPOSITION: September 9, 1948. Default decree of condemnation and destruction.

2558. Adulteration of dextrose in distilled water. U. S. v. 30 Flasks * * *. (F. D. C. No. 25453. Sample No. 4838–K.)

LIBEL FILED: August 13, 1948, District of Massachusetts.

ALLEGED SHIPMENT: On or about October 28, 1946, from Cleveland, Ohio.

PRODUCT: 30 flasks of *dextrose in distilled water* at Worcester, Mass. The product was in hermetically sealed flasks and was intended for intravenous injection.

LABEL, IN PART: "Dextrose 10% W/V in Distilled Water 1000 cc."

NATURE OF CHARGE: Adulteration, Section 501 (b), the article purported to be and was represented as "Dextrose Injection," the name of which is recognized in the United States Pharmacopoeia, and its quality and purity fell below the official standard since the standard provides that injections must be substan-

*See also No. 2596.

tially free of undissolved material, whereas the article was contaminated with undissolved material. The article was adulterated while held for sale after shipment in interstate commerce.

DISPOSITION: September 27, 1948. Default decree of condemnation and destruction.

2559. Adulteration and misbranding of dextrose solution and adulteration of sodium chloride solution. U. S. v. 330 Flasks, etc. (F. D. C. No. 25095. Sample Nos. 18071–K, 18073–K.)

LIBEL FILED: July 20, 1948, Southern District of Indiana.

ALLEGED SHIPMENT: During the period of March 14, 1947, to March 8, 1948, by the Continental Pharmacal Co., from Cleveland, Ohio.

PRODUCT: 330 flasks of *dextrose solution* and 36 flasks of *sodium chloride solution* at Indianapolis, Ind.

LABEL, IN PART: "Dextrose 5% in Isotonic Solution of Sodium Chloride 500 cc. * * * sterile and nonpyrogenic" and "Isotonic Solution of Sodium Chloride U. S. P. 500 cc."

NATURE OF CHARGE: Adulteration, Section 501 (b), the articles purported to be and were represented as "Dextrose and Sodium Chloride Injection" and "Sterile Isotonic Sodium Chloride Solution for Parenteral Use," respectively, drugs the names of which are recognized in the United States Pharmacopoeia, an official compendium, and their quality and purity fell below the official standards since the articles were contaminated with undissolved material; and the *dextrose solution* was contaminated with living micro-organisms and pyrogen.

Misbranding, Section 502 (a), the statement "This product is sterile and non-pyrogenic" on the label of the *dextrose solution* was false and misleading.

DISPOSITION: September 24, 1948. Default decree of forfeiture and destruction.

2560. Adulteration and misbranding of dextrose in isotonic solution of sodium chloride. U. S. v. 14 Flasks * * *. (F. D. C. No. 25357. Sample Nos. 6696–K, 6708–K.)

LIBEL FILED: August 11, 1948, Western District of New York.

ALLEGED SHIPMENT: On or about June 3, 1947, by the Continental Pharmacal Co., from Cleveland, Ohio.

PRODUCT: 14 flasks of *dextrose in isotonic solution of sodium chloride* at Gowanda, N. Y. The solution was contained in hermetically sealed flasks and was intended for intravenous injection. That intravenous use was contemplated was evidenced by the statement on the flask label "For the purpose of filling and rinsing the tubing this unit contains 50 cc in excess of the declared volume * * * Single dose container."

LABEL, IN PART: "Dextrose 5% In Isotonic Solution of Sodium Chloride 1000 cc * * * sterile and non-pyrogenic."

NATURE OF CHARGE: Adulteration, Section 501 (b), the article purported to be and was represented as "Dextrose Injection in Isotonic Sodium Chloride Solution," a drug the name of which is recognized in the United States Pharmacopoeia, an official compendium, and the quality and purity of the article fell below the official standard since it was contaminated with living micro-organisms and contained pyrogen.

Misbranding, Section 502 (a), the label statement "This product is sterile and non-pyrogenic" was false and misleading as applied to an article contaminated with living micro-organisms and pyrogen.

DISPOSITION: September 13, 1948. Default decree of condemnation. The product was ordered delivered to the Food and Drug Administration, for testing purposes.

2561. Adulteration of sodium iodide and sodium salicylate. U. S. v. 67 Ampuls * * *. (F. D. C. No. 23967. Sample Nos. 79517–H, 14603–K.)

LIBEL FILED: On November 24, 1947, Northern District of Illinois.

ALLEGED SHIPMENT: On or about July 18, 1947, by Bristol Laboratories, Inc., from Syracuse, N. Y.

PRODUCT: 67 ampuls of *sodium iodide and sodium salicylate* at Chicago, Ill.

LABEL, IN PART: "20 cc. size ampuls Sodium Iodide and Sodium Salicylate Sterile Solution for Intravenous Use."

NATURE OF CHARGE: Adulteration, Section 501 (b), the product purported to be and was represented as a drug, "Sodium Salicylate and Iodide Ampuls," the name of which is recognized in the National Formulary, an official compendium, and its quality and purity fell below the standard set forth in the compendium since it was contaminated with undissolved material.

DISPOSITION: February 3, 1948. Default decree of condemnation and destruction.

2562. Adulteration of sodium salicylate and iodide with colchicine. U. S. v. 4 Cartons * * *. (F. D. C. No. 25415. Sample No. 46005–K.)

LIBEL FILED: August 26, 1948, Eastern District of Missouri.

ALLEGED SHIPMENT: On or about June 11, 1948, from Philadelphia, Pa.

PRODUCT: 4 cartons, each containing 12 20-cc ampuls, of *sodium salicylate and iodide with colchicine* at St. Louis, Mo.

NATURE OF CHARGE: Adulteration, Section 501 (b), the article purported to be and was represented as "Sodium Salicylate and Iodide with Colchicine Ampuls," a drug the name of which is recognized in the National Formulary, an official compendium, and its quality and purity fell below the official standard since it was contaminated with undissolved material. The article was adulterated while held for sale after shipment in interstate commerce.

DISPOSITION: January 6, 1949. Default decree of condemnation and destruction.

2563. Adulteration of vitamin B complex with distilled water. U. S. v. 92 Packages * * *. (F. D. C. No. 25631. Sample No. 25868–K.)

LIBEL FILED: September 11, 1948, District of Minnesota.

ALLEGED SHIPMENT: On or about August 4, 1948, by Hyland Laboratories, from Los Angeles, Calif.

PRODUCT: 92 packages of *vitamin B complex with distilled water* at Minneapolis, Minn.

LABEL, IN PART: "10cc. B-Complex dried * * * with sterile diluent containing * * * Distilled Water 10cc."

NATURE OF CHARGE: Adulteration, Section 501 (c), the diluent purported to be and was represented as "Water for Injection," a drug the name of which is recognized in the United States Pharmacopoeia, an official compendium, and

its quality and purity fell below the official standard since the diluent was contaminated with undissolved material.

DISPOSITION: January 6, 1949. Default decree of destruction.

2564. Adulteration of thiamine hydrochloride solution. U. S. v. 61 Vials, etc. (F. D. C. No. 25419. Sample No. 19533–K.)

LIBEL FILED: September 1, 1948, Middle District of Tenessee.

ALLEGED SHIPMENT: On or about May 25, 1948, from Los Angeles, Calif.

PRODUCT: 61 30-cc. vials and 97 10-cc. vials of *thiamine hydrochloride solution* at Nashville, Tenn.

LABEL, IN PART: "Sterile solution Thiamine Hydrochloride * * * For Intramuscular or Intravenous Use."

NATURE OF CHARGE: Adulteration, Section 501 (b), the article purported to be and was represented as "Thiamine Hydrochloride Injection," a drug the name of which is recognized in the United States Pharmacopoeia, an official compendium, and its quality and purity fell below the official standard since it was contaminated with undissolved material. The article was adulterated while held for sale after shipment in interstate commerce.

DISPOSITION: December 22, 1948. Default decree of destruction.

2565. Adulteration of vitamin B_1 and liver extract. U. S. v. 172 Vials, etc. (F. D. C. No. 25507. Sample Nos. 30353–K, 30355–K, 30357–K.)

LIBEL FILED: August 31, 1948, Southern District of California.

ALLEGED SHIPMENT: On or about February 19, March 11, and May 28, 1948, from Detroit, Mich.

PRODUCT: 172 30-cc. vials of *vitamin B_1* and 49 10-cc. vials of *liver extract* at Los Angeles, Calif.

LABEL, IN PART: "Vitamin B_1 (Thiamine Chloride) * * * Administer intravenously or intramuscularly" and "Liver Extract Injectable."

NATURE OF CHARGE: The products were adulterated while held for sale after shipment in interstate commerce under Section 501 (b), in that they purported to be and were represented respectively as "Thiamine Hydrochloride Injection" and "Liver Injection," drugs the names of which are recognized in the United States Pharmacopeia, and their quality and purity fell below the official standards since the vitamin B_1 was contaminated with undissolved material and the *liver extract* was contaminated with heavy turbidity and precipitate.

DISPOSITION: October 20, 1948. Default decree of condemnation and destruction.

2566. Adulteration and misbranding of liver extract. U. S. v. 46 Vials * * *. (F. D. C. No. 25630. Sample No. 30356–K.)

LIBEL FILED: September 9, 1948, Southern District of California.

ALLEGED SHIPMENT: On or about June 30, 1948, by Sherman Laboratories, from Detroit, Mich.

PRODUCT: 46 vials of *liver extract* at Los Angeles, Calif.

LABEL, IN PART: "10 cc. Size Liver Extract Injectable 10 Units per cc. Sterile for intramuscular use."

NATURE OF CHARGE: Adulteration, Section 501 (b), the article purported to be and was represented as a drug, "Liver Injection," the name of which is recognized in the United States Pharmacopoeia, and its quality and purity fell

below the standard set forth in the Pharmacopoeia since it was contaminated with viable micro-organisms.

Misbranding, Section 502 (a), the label statement "Sterile" was false and misleading.

DISPOSITION: October 19, 1948. Default decree of condemnation and destruction.

2567. Adulteration of ammoniated mercury ointment and methenamine ampuls. U. S. v. Barlow-Maney Laboratories, Inc. Plea of guilty. Fine, $250 and costs. (F. D. C. No. 25568. Sample Nos. 14510–K, 26351–K.)

INFORMATION FILED: September 28, 1948, Northern District of Iowa, against Barlow-Maney Laboratories, Inc., Cedar Rapids, Iowa.

ALLEGED SHIPMENT: On or about October 21 and 28, 1947, from the State of Iowa into the States of Illinois and Missouri.

NATURE OF CHARGE: *Ammoniated mercury ointment.* Adulteration, Section 501 (c), the strength of the article differed from that which it was represented to possess since it was represented to possess a strength of 10 percent ammoniated mercury, whereas it possessed a strength of less than that amount.

Methenamine ampuls. Adulteration, Section 501 (b), the article purported to be and was represented as "Methenamine Ampuls," a drug the name of which is recognized in the National Formulary, an official compendium, and its strength differed from the official standard since it contained less than 96 percent of the labeled amount of methenamine, the minimum permitted by the standard; and its difference in strength from the standard was not plainly stated, or stated at all, on its labeling.

DISPOSITION: September 28, 1948. A plea of guilty having been entered, the court imposed a fine of $250 and costs.

2568. Adulteration of pentnucleotide. U. S. v. 2 Cartons * * *. (F. D. C. No. 25544. Sample No. 2820–K.)

LIBEL FILED: August 31, 1948, District of Maryland.

ALLEGED SHIPMENT: On or about July 9, 1948, by Smith, Kline & French Laboratories, from Philadelphia, Pa.

PRODUCT: 2 cartons, each containing 16 10-cc. size vials, of pentnucleotide at Baltimore, Md.

NATURE OF CHARGE: Adulteration, Section 501 (c), the purity and quality of the article fell below that which it purported and was represented to possess, namely (carton label) "Pentnucleotide * * * for intramuscular use" since the article contained excessive quantities of undissolved material, whereas an article which is represented for parenteral use should be substantially free of any undissolved material.

DISPOSITION: October 6, 1948. Default decree of condemnation and destruction.

2569. Adulteration of protein hydrolysate solution. U. S. v. 22 Vials * * *. (F. D. C. No. 25514. Sample No. 8174–K.)

LIBEL FILED: August 30, 1948, District of Connecticut.

ALLEGED SHIPMENT: On or about January 16, 1948, from Detroit, Mich.

PRODUCT: 22 100-cc. vials of *protein hydrolysate solution* at Hartford, Conn.

NATURE OF CHARGE: Adulteration, Section 501 (c), the purity and quality of the article fell below that which it purported and was represented to possess,

namely, "Protein Hydrolysate sterile solution 15% parenteral." The article contained excessive quantities of undissolved material, whereas an article which is represented for parenteral use should be substantially free of any undissolved material. The article was adulterated while held for sale after shipment in interstate commerce.

DISPOSITION: November 29, 1948. Default decree of condemnation and destruction.

2570. Adulteration and misbranding of Aquadiol. U. S. v. 46 Vials, etc. (F. D. C. No. 25251. Sample Nos. 26585–K, 46008–K, 46009–K.)

LIBEL FILED: August 11, 1948, Eastern District of Missouri.

ALLEGED SHIPMENT: On or about January 29 and June 4, 1948, by the National Drug Co., from Philadelphia, Pa.

PRODUCT: 46 vials and 213 vials of *Aquadiol* at St. Louis, Mo. Examination showed that the 46-vial lot contained less than 0.074 milligram and that the 213-vial lot contained less than 0.12 milligram, of alpha-estradiol per cubic centimeter.

NATURE OF CHARGE: Adulteration, Section 501 (c), the strength of the article differed from that which it was represented to possess, namely, (46-vial lot) 0.11 milligram and (213-vial lot) 0.22 milligram of alpha-estradiol per cubic centimeter.

Misbranding, Section 502 (a), the label statements (46-vial lot) "per cc. 0.11 mg alpha Estradiol" and (213-vial lot) "per cc. 0.22 mg alpha Estradiol" were false and misleading.

DISPOSITION: December 3, 1948. Default decree of condemnation and destruction.

2571. Adulteration and misbranding of Anademin Tablets and Arner Formula No. 37,200 Special Formula Tablets. U. S. v. 247 Packages, etc. (F. D. C. No. 25421. Sample Nos. 19545–K to 19548–K, incl.)

LIBEL FILED: September 1, 1948, Eastern District of Tennessee.

ALLEGED SHIPMENT: On or about November 20 and 24, 1947, and June 28 and July 1 and 6, 1948, by the Arner Co., Inc., from Buffalo, N. Y.

PRODUCT: 247 100-tablet packages of *Anademin Tablets* and 45 drums, each containing 45,000 tablets, of *Arner Formula No. 37,200 Special Formula Tablets* at Chattanooga, Tenn. Examination showed that the potency of each tablet was equivalent to less than two-thirds of a U. S. P. digitalis unit.

NATURE OF CHARGE: Adulteration, Section 501 (c), the strength of the tablets differed from that which they were represented to possess, namely, "one U. S. P. digitalis unit."

Misbranding, Section 502 (a), the statement on the drum and package labels of the tablets "Each tablet is equivalent in potency to one U. S. P. digitalis unit" was false and misleading as applied to an article containing less than two-thirds U. S. P. digitalis unit.

DISPOSITION: October 13, 1948. The Anademin Chemical Co., Chattanooga, Tenn., having appeared as claimant, judgment of condemnation was entered and the product was ordered released under bond to be brought into compliance with the law, under the supervision of the Federal Security Agency.

2572. Adulteration and misbranding of Neidig Chiro Antiseptic Powder. U. S. v. Arthur M. Neidig (E. S. Neidig). Pleas of nolo contendere. Sentence suspended and defendant placed on probation for 3 years. (F. D. C. No. 24264. Sample No. 70169–H.)

INFORMATION FILED: June 17, 1948, Middle District of Pennsylvania, against Arthur M. Neidig, trading as E. S. Neidig at Sunbury, Pa.

ALLEGED SHIPMENT: On or about July 24, 1947, from the State of Pennsylvania into the State of Michigan.

PRODUCT: Analysis disclosed that the product consisted of 30.5 percent of dehydrated sodium borate, 47.6 percent of anhydrous sodium carbonate, and 21.9 percent of water of crystallization, and that the product failed to exhibit either inhibitory antiseptic, germicidal, or fungicidal properties.

NATURE OF CHARGE: Adulteration Section 501 (c), the strength of the article differed from and its quality fell below that which it was represented to possess since it was represented to be an antiseptic and it was not an antiseptic.

Misbranding, Section 502 (a), certain statements in the labeling of the article were false and misleading since they represented and suggested that the article was an antiseptic; that it would be efficacious in the cure, mitigation, and treatment of coughs, sore throat, dyspepsia, indigestion, stomach troubles, nasal catarrh, injuries and infections of the skin, psoriasis, hives, shingles, cuts, scalds, burns, itch, ringworm, athlete's foot, bedsores, barber's itch, erysipelas, eczema, dandruff, boils, abscesses, carbuncles, dangerous wounds by splinters, firearms, and rusty nails, dog and snake bites, open sores, ulcers, gastric ulcers, arthritis, rheumatism, infections of the alimentary canal, acid indigestion, gastritis, intestinal catarrh, diarrhea, sugar diabetes, yellow jaundice, colitis, convulsions, amoebic dysentery, gastrointestinal fermentation, ptomaine poisoning, gall trouble, typhoid fever, inflamed eyes and sties, running ear, nose bleed, infections of the mucous membranes, croup, hoarseness, hiccoughs, tonsillitis, diphtheria, quinsy, tuberculosis, septic sore throat, colds, tuberculosis of the lungs, asthma, bronchitis, bronchial catarrh, laryngitis, influenza, pneumonia, hay fever, babies' troubles, sore mouth, irritations, sores, fever, constipation, leucorrhea, piles, hemorrhoids, fistula, fissures, eating cancers, appendicitis, disease of the prostate gland, pyorrhea, enlarged adenoids, small goiters, sinus infection, proud flesh, astigmatism, cataract on the eyes, blood poison, fibroid tumors, cancers, worms, lump in breast, cancer of eye, cancer of rectum, sore foot, swollen throat, sore leg, chronic colitis, high fever, vaginal ulcers, gangrene, diabetes, dropsy, scarlet fever, flooding spells, bowel trouble, inward trouble, hemorrhages, itching of vagina, infection, gallstones, kidney stones, tape worm, protruding piles, cyst, bleeding piles, mastoids, cataracts, infected eye, discharge from ears, sore eyes, St. Vitus's dance, prostate gland trouble, bloat, infected tonsils, toothache, blisters, flu, upset stomach, cauliflower cancer, blood clot, adhesions, and cold on the chest; that the article would be efficacious to sterilize the hands, face, and mouth, and to destroy all bacteria and rid mucus of the germs it contains; that it could be safely eaten and drunk; that it would act on disease the same as soap acts on dirt; that it would be efficacious to destroy bacterial life, the cause of diseases such as T. B.; that it would be efficacious to keep the vaginal tract healthy, to destroy any infection from a mosquito bite to social disease, to prevent and protect against disease and infections, to prevent pus formation and diptheria, and to break up any sore throat overnight and any fever in one hour; and that it would be efficacious to keep the blood stream pure. The article was not an

antiseptic; it could not be safely eaten and drunk and it would not be efficacious for the purposes represented.

DISPOSITION: January 12, 1949. A plea of nolo contrendere having been entered, the court suspended the imposition of sentence and placed the defendant on probation for 5 years, conditioned that he discontinue all misbranding of the article, seek the review and advice of the Food and Drug Administration, and refrain from any label, labeling, or claims regarding the article which would be contrary to the law, regulations, and opinions of the Food and Drug Administration.

2573. Alleged violation of injunction. U. S. v. Dean Rubber Co., et al. Defendant judged not guilty. (Inj. No. 3.)

INFORMATION FILED: On June 7, 1946, Western District of Missouri, against the Dean Rubber Co., a corporation, North Kansas City, Mo., and against Wilbur J. Dean, Charles H. Fry, Beulah V. Dean, Ralph A. Briant, Carl Wormington, Morris J. Pollock, Justine Woodard, Ruth Marie Symons, W. R. Adelsperger, Claiborne Dean, Alpha Dean, Archie Dean, Viola Bausin, and Harry Custer, copartners, doing business as the Dean Rubber Co.; amended informations filed August 6 and October 28, 1946, and March 11, 1947.

ALLEGED VIOLATION: The first information alleged that on September 11, 1940, a permanent injunction, as reported in notices of judgment on drugs and devices, No. 409, had been entered enjoining the Dean Rubber Co., its officers, agents, and all persons then or thereafter acting by or through them, from distributing in interstate commerce any *prophylactics* containing holes or which might subsequently acquire holes; that at that time, one Wilbur J. Dean, was and continued to be president and acting manager of the Dean Rubber Co., a corporation; that on or about October 21, 1944, the assets and business of the corporation were transferred to Wilbur J. Dean, Beulah V. Dean, Charles H. Fry, Ralph A. Briant, Carl Wormington, Morris J. Pollock, Justine Woodard, Ruth Marie Symons, W. R. Adelsperger, Claiborne Dean, Alpha Dean, Archie Dean, Viola Bausin, and Harry Custer, who since that time had operated as copartners under the name of Dean Rubber Co.; that the corporation, Wilbur J. Dean, and each of the other defendants had actual knowledge of the contents of the decree for permanent injunction; that in willful violation of the injunction and in contempt of the court, the defendants had on or about September 30, October 25, and December 14, 1944, and on or about January 9 and 30, February 2, 6, 14, and 17, June 4 and 9, and July 6 and 29, 1945, willfully, unlawfully, contumaciously, and contemptuously caused to be shipped in interstate commerce various quantities of *prophylactics* which were adulterated under Section 501 (c) and misbranded under Section 502 (a), by the reason of containing holes.

DISPOSITION: Upon the filing of the original information on June 7, 1946, an order to show cause why defendants should not be held in contempt of court was issued. Thereafter, the first amended information was filed to include additional violative shipments which were caused to be made by the defendant on or about April 14 and 18 and July 13, 1944, October 17 and December 6 and 7, 1945, and January 22 and 23, February 6, and March 15, 1946. A motion for dismissal of this amended information was then filed on behalf or the defendants, and on October 7, 1946, the court handed down the following opinion in regard to such motion:

RIDGE, *District Judge:* "The amended information filed herein alleges that on September 11, 1940, a permanent injunction was entered against the Dean

Rubber Company, a Corporation, by which said defendant, its officers and agents and all persons then or thereafter acting by, through or under it or them, were perpetually enjoined and restrained from distributing, in interstate commerce, 'any of the stock of defective rubber prophylactics which it had on hand at Kansas City, Missouri, or at any other point, or any other quantity of defective rubber prophylactics it might subsequently acquire.'

"In Paragraph 2 of the information it is alleged that W. J. Dean was the President and Acting Manager of said Dean Rubber Company, a Corporation; that on or about the 21st day of October, 1944, the assets and business of said Corporation were transferred to certain individuals who, since that time, have been and are now operating as co-partners under the style and trade name of Dean Rubber Company; that at the time of such transfer 'each of the within-named individual defendants had actual knowledge of the contents of said injunction order.'

"Rule 65 (d) F. R. C. P. provides that an order granting an injunction 'is binding only upon the parties to the action, and officers, agents, servants, employees, and attorneys, and upon those persons in active concert or participation with them who receive actual notice of the order by personal service or otherwise.' Under said rule mere knowledge, in and of itself, of the issuance of an injunction would not make a person, not a party to an injunction suit, liable to contempt proceedings for committing an independent act not done in 'active concert or participation with' a party bound by the injunction. *Alemite Mfg. Co.* v. *Staff*, 42 F. (2d) 832; *Harvey* v. *Bettis*, 35 F. (2d) 349. The amended information does not allege how or in what manner the alleged individual contemnors, named therein, acted in concert or participation with the corporate defendant in violating the injunctive decree. All that is alleged in the 3rd and subsequent paragraphs of the information is that 'said defendants did wilfully, unlawfully, contumaciously and contemptuously ship and cause to be shipped in interstate commerce' certain defective rubber prophylactics. There was only one defendant in the original action, namely, the Dean Rubber Manufacturing Company, a Corporation. If the individuals named in the amended information are guilty of violating the injunction decree of this Court, then they are 'contemnors' and not defendants, and the information must allege a 'privity' between defendant and said individuals.

"In its suggestions in opposition to the motion to dismiss the Government states 'the corporation, for some reason, did transfer its assets but, at the same time retained its legal entity and continued in active operation of its business.' If such be a fact, then the amended information should be amended and the facts set out concerning such matters. As the information now stands no such issue is presented. All that is alleged, in the instant information, is a succession to the assets of the business of the corporation by the individuals named as alleged contemnors therein. It is doubtful whether an assignment alone is sufficient to make the assignee bound by an injunction decree. The facts showing the privity between the original parties to the suit and the assignee, or stranger to the action should be alleged so that the information, upon its face, shows a mutual or successive relationship of such parties to the subject matter of the injunction decree.

"It is noted that the injunction decree in part is in personam and in part in rem, i. e., the injunction decree enjoins the corporation from distributing, in interstate commerce, 'any of the stock of defective rubber prophylactics which it now has on hand.' That portion of said decree is in rem. The prohibition of the decree which enjoins distributing in interstate commerce,

'any other quantity of defective rubber prophylactics which it may subsequently acquire,' is in personam. It is only injunctions, acting in rem, that bind successive ownerships of the rem. *Rivera* v. *Lawton*, 42 F. (2d) 832. 28 Am. Jur. p. 505, etc. Only persons who are parties to an injunction decree, or in privity with those whose rights have been adjudicated thereby, are bound by a personam decree. *Chase Nat'l. Bank* v. *Norwalk*, 291 U. S. 431.

"In view of the statement contained in plaintiff's suggestions that 'the evidence on behalf of the plaintiff will disclose that the individual defendants were employees or officers of the corporation at the time judgment was entered against it' and it appears that plaintiff contends that the individual contemnors are 'acting by, through or under' Dean Rubber Manufacturing Company, or that perhaps said individuals were the sole owners of the stock of said corporation at the time the injunction was granted, plaintiff will be given leave to amend its amended information so as to state the facts concerning the privity existing between said corporation and the individual contemnors. If plaintiff does not file an amended information within ten days, defendant's motion to dismiss will be sustained.

"It Is So Ordered."

As a result of the foregoing opinion, the second amended information was filed, following which a motion for a bill of particulars was filed on behalf of the defendants. The motion requested information as to (1, a) whether the *prophylactics* so shipped were those which the defendant, the Dean Rubber Co., a corporation, had on hand on September 11, 1940; or had subsequently acquired; (1, b) whether the *prophylactics* at the time of the shipment were owned and shipped by the individual defendants as partners; (2) what part of the assets of the defendant, the Dean Rubber Co., a corporation, were transferred to the individual defendants, what was the date of transfer, and whether or not the corporation had since the transfer continued to ship *prophylactics* in interstate commerce and operated the business; (3) whether or not the individual defendants or any of them at the time of the shipments were "acting by, through or under" the corporation, as set forth in the last paragraph of the court opinion of October 7, 1946; (4, a) whether or not the individual defendants or any of them were at the times of the shipments in "active concert or participation with" the corporation as set forth in the court's opinion of October 7, 1946; and (4, b) how and in what manner the individual defendants or any of them were in "active concert of participation with" the corporation, as set forth in the court's opinion of October 7, 1946. On January 30, 1947, the court handed down the following opinion on the motion for a bill of particulars:

Ridge, *District Judge:* "From a perusal of the Government's Second Amended Information, it appears that this criminal contempt proceeding against defendant and the individual contemnors is premised upon the proposition that said parties are acting in concert or participation with each other to violate the injunctive decree of this Court. Such being the predicate of this proceeding, it is not necessary that the information set forth whether the prophylactics shipped were those which defendant Dean Rubber *Manufacturing* Company had on hand on September 11, 1940, as requested in specification 1 (a) of defendants' 'Motion for Bill of Particulars.' Such facts would only be material if the information was premised upon a 'successive' relationship between said parties concerning the 'rem' of the injunctive decree. If the latter is a premise of the contempt proceeding, then the information sought in the above specification should be alleged in the information.

"The 'ownership' of the prophylactics shipped is immaterial in determining

the guilt or innocence of the individual contemnors. If said parties acted in concert with defendant Dean Rubber *Manufacturing* Company, in violation of the injunctive decree, then regardless of the ownership of such goods, or how such parties became possessed thereof, is not pertinent, except perhaps from a defensive standpoint. Defendants' specification 1 (b) of Motion for Bill of Particulars is overruled.

"The information sought in specification 2 of said motion is evidentiary and need not be stated in the information. The present allegations of the information allege that *Dean Rubber Company* shipped or caused to be shipped in interstate commerce the prophylactics in question. Specification 2, of said motion is overruled.

"Specifications 3, 4 (a) and (b) of said motion are sustained. The information, or other formal statement, by which the prosecution of a contempt proceeding is initiated, should state completely the necessary facts constituting the offense so that the parties charged may be clearly apprised of the nature of the charge against them and the acts complained of. Technical accuracy, however, is not required. In the original injunction proceeding the defendant was the Dean Rubber Manufacturing Company, a corporation, not Dean Rubber Company, a corporation. The original defendant in the injunction case has not been made a party in this contempt proceeding. Perhaps this is an oversight but it should be clarified now before any other action is taken herein.

"As above stated, it appears that this contempt proceeding is based on 'concert of action' between the parties named in the information as defendants. I do not believe 'concert of action' alleged to be the cause of the violation of an injunction, can be premised on an assignment of assets alone, unless the injunction decree is directly concerned with the assets transferred, or the assignment is made for the purpose of evading the terms of the injunction decree. *Le Tourneau Co. etc.* v. *N. L. R. B., 150 Fed. (2d) 1012; Holcomb & Co.* v. *U. S. 180 Fed. 794; Hoover Co.* v. *Exchange Vacuum Cleaner Co., 1 F. Supp. 997.* However, where a successor in interest takes over the entire business of one bound by an injunction decree and the conduct of that business is the basis for the injunction, he would probably be liable for a violation of the injunction if the successor in interest conducted such business in the same manner as his assignor had conducted it. *Schumacher* v. *Shawhan Dis. Co. (Mo. App.) 165 S. W. 1142; Riviera* v. *Lawton, 35 Fed. (2d) 823.* I make the above observations because I do not believe that the Second Amended Information alleges sufficient facts to establish 'active concert or participation' by the individual contemnors in a violation of the decree in question. The Government must allege facts in its information, so showing, before a cause for action by this Court can be taken in the premises. *Edwards* v. *U. S., 123 Fed. (2d) 465.* If the individuals are the 'alter egos' of the Dean Rubber Manufacturing Company, facts establishing that relation should be stated in the information. If they are 'successors in interest' under such circumstances as to make them bound by an injunction issued against their assignor, then the facts creating such environment should be alleged. From the allegations of the present information the Court cannot determine which relationship the individuals are sought to be charged. Under such circumstance, the instant Information does not comport with the requirements of proper pleading in a Criminal Contempt Proceeding.

"This is such a contempt proceeding. *Bullock Elec. & Mfg. Co.* v. *Westinghouse, etc., 129 Fed. 105; Nye* v. *U. S. 313 U. S. 33; Gompers* v. *Bucks Stove, etc. 221 U. S. 418.* The action is brought in the name of the United States and

the punishment, if assessed, would be punitive. *Phillips, etc.* v. *Amalgamated, etc., 208 Fed. 335.*

"The Government is given twenty (20) days in which to file an Amended Information in conformance to this order.

"It Is So Ordered."

In accordance with the foregoing opinion, the third amended information was filed to name correctly the corporate defendant and to recite more precisely the privity between the corporation and the individuals. A motion to dismiss this information was filed on April 4, 1947, and on August 1, 1947, the following opinion was handed down by the court, denying the motion:

Ridge, *District Judge:* "Contemnors herein have moved to dismiss the 'Third Amended Information' on the ground that the several alleged criminal violations of the injunctive decree charged therein, having occurred more than one year before the filing of said information, are barred by limitations provided in *28 U. S. C. A. 390* (*Section 25 of the Clayton Act*).

"The final injunction decree upon which said information is premised was entered on September 11, 1940, in an action instituted by the United States for that purpose, perpetually enjoining and restraining the Dean Rubber Manufacturing Company, a corporation, its officers and agents, and persons then or thereafter acting by, through or under it, or them, from distributing in interstate commerce any of the stock of defective rubber prophylactics which it then had on hand at North Kansas City, Missouri, or at any other point, or any other quantity of defective rubber prophylactics which it might subsequently acquire, 'defective,' within the meaning of the order; except in compliance with *Section 381* (*d*), *U. S. C. A., Title 21* (*The Federal Food, Drug and Cosmetic Act*) (*52 Stat. 1041, etc.*).

"*Section 302* (*b*) *of the Federal Food, Drug and Cosmetic Act* (*52 Stat. 1043; Title 21, Section 332* (*b*), *U. S. C. A.*), provides that 'in case of violation of an injunction * * * issued under (the act), which also constitutes a violation of (the act) * * *' the trial for such violation may be before the Court, or a jury if requested, and 'shall be conducted in accordance with the practice and procedure applicable in the case of proceedings subject to the provisions of *Section 387 of Title 28*, as amended.'

"*Section 387 of Title 28*, in *Section 22 of the Clayton Act.* The Clayton Act governs the procedure in criminal contempts which consist of 'criminal offenses' under any statute of the United States or of any State, except insofar as certain contempts are expressly excluded from its terms. The Clayton Act is neither a grant nor a limitation on the powers of the Federal Courts to punish for contempts, but only prescribes and limits the procedure as to punishment for contempts within the purview thereof. After enumerating the contempts as to which the procedure of the Clayton Act is to be followed, *Section 24* of said Act (*Title 28, Section 391, U. S. C. A.*) expressly excludes from its operations, (1) contempts committed in, or near to, the presence of the Court as to obstruct the administration of justice, and (2) 'contempts committed in disobedience of any lawful writ, process, order, rule, decree, or command entered in any suit or action brought or prosecuted in the name of, or on behalf of, the United States.' As to the latter excluded criminal contempts from the provisions of the Clayton Act, it is held that they fall under the general three-year statute of limitation (*Title 18, Section 582, U. S. C. A.*) *U. S.* v. *Goldman, 277 U. S. 229; Hill* v. *U. S. ex rel. Weiner, 300 U. S. 105;* and that as provided in *Section 24* of said Act (*Title 28, Section 389, U. S. C. A.*), punishment therefor may be assessed 'in conformity to the usages at law and in equity prevailing on October

15, 1914'. If the instant action was prosecuted by the United States under the Anti-Trust Act, or similar Act of Congress, there could be no doubt but that the alleged criminal contempts here sought to be prosecuted would not be barred by the one-year period of limitation provided in *Section 25 of the Clayton Act* (*Title 28, U. S. C. A., 390*), *U. S.* v. *Goldman and Hill* v. *U. S., supra.*

"Contemnors maintain, however, that *Section 302* (*b*) of the *Federal Food, Drug, and Cosmetic Act, supra.*, by expressly subjecting proceedings for violations of injunctions under that Act to the same rules as proceedings under *Section 22* of the *Clayton Act, supra.*, made an 'exception to the exception' contained in the Clayton Act as to criminal contempts prosecuted by the United States, because all proceedings instituted for the enforcement, or to restrain violations of the Federal Food, Drug and Cosmetic Act, are brought in the name of the United States. (*21 U. S. C. A. 537*). They say, 'what a futile thing would Congress have done if * * * all injunction violations under the Food and Drug Act are governed the same as proceedings under *Section 387*, but since *Section 389* (*Title 28 U. S. C. A., Sections 387, 389*) exempts all such proceedings, Congress merely put such proceedings within the Clayton Act and by the same words took them out from under the Clayton Act.'

"Section 302 (b) of the *Federal Food, Drug, and Cosmetic Act* (*Title 21, U. S. C. A. 332* (*b*)) did not place criminal contempt proceedings for violations of injunctions procured by the United States, under the Food and Drug Act within the purview of all the provisions of the Clayton Act. All that is accomplished by the provisions of *Section 302* (*b*) *supra.*, is to incorporate into the Federal Food, Drug, and Cosmetic Act one section of the Clayton Act (Section 22) which section sets up a procedure to be followed in the trial and punishment of contempts for violations of an injunction procured under the Federal Food, Drug and Cosmetic Act. Notice the language used in *Section 302* (*b*), *supra.*, is that 'trials' for contempt in case of violation of an injunction procured under the Federal Food, Drug and Cosmetic Act are to 'be conducted in accordance with the practice and procedure applicable in the case of *proceedings subject to the provisions of* Section 387 of Title 28, as amended.' The only 'proceedings' that are 'subject to the provisions of Section 387,' supra., are criminal contempt proceedings arising in litigations where the 'order * * * decree or command entered is not in a suit or action brought or prosecuted in the name of, or on behalf of, the United States.' In other words, in litigation of a private nature, and such criminal contempts as are committed and prosecuted under miscellaneous Federal statutes authorizing punishment for contempt without designating the particular contempt as civil or criminal and generally containing no provisions as to procedure, as in the Federal Rules of Civil Procedure. (See *Rules 37* (*b*) (*1*); *45* (*f*); *56* (*g*) *and 70.*) In providing that *Section 22* of the Clayton Act shall be the procedure to be followed in prosecution of alleged contempts for violation of injunctions procured under the Federal Food, Drug and Cosmetic Act, Congress established a limited special procedure to be followed in such cases and took such contempt actions out of the procedure generally followed 'at law and in equity' in cases wherein the United States was the party procuring an injunction decree or order. Without such limitation contained in *Section 302* (*b*) of the *Federal Food, Drug and Cosmetic Act*, the alleged contumacious conduct here charged against contemnors would be prosecuted under *Section 268* of the *Judicial Code* (*Title 28, U. S. C. A. 385*). In changing the procedure previously established as to criminal contempts prosecuted in the name of the United States so far as such contempts may arise under the Federal Food, Drug, and Cosmetic Act, Congress did not provide that other sections of

the Clayton Act (other than *Section 22* thereof), be made applicable to contempt proceedings arising under the Federal Food, Drug and Cosmetic Act, as asserted by contemnors. To sustain such contention would work the anomalous situation which contemnors state, namely, that Congress 'put such proceedings within the Clayton Act and by the same words took them out from the Clayton Act.' *Section 24* of the Clayton Act (*Title 28 U. S. C. A. 389*) would produce such a paradoxical result. Under contemnors' position, all the sections of the Clayton Act relating to contempt proceedings must be presumed to have been intended by Congress to apply to criminal contempt proceedings instituted under the Federal Food, Drug and Cosmetic Act, and not only *Sections 22 and 25* thereof (*Title 28, U. S. C. A. 390*). To make such assumption is to charge Congress with being a paradoxer. Congress cannot be so charged with such self-annulling action as asserted by contemnors.

"*Section 24* of the Clayton Act, supra, is not specifically made to apply to contempt proceedings instituted under the Federal Food, Drug and Cosmetic Act as is *Section 22* of said Act. *Section 24* of the Clayton Act establishes a limitation of action. A statute creating a limitation against the bringing of an action is never assumed to be effective as against actions instituted by the Federal Government and is only effective against such actions when specifically made so. Exemption from statutes of limitation ordinarily is implied in favor of the State and Federal Governments (*34 Am. Jur. 303, etc.*).

"From what has been heretofore said, it is not necessary to discuss other points raised by contemnors in their briefs.

ORDER

"Contemnors' motion to dismiss this action is by the Court overruled."

On October 26, 1948, after further consideration of the entire matter, the court found the corporation and the individuals not guilty of contempt.

2574. Adulteration and misbranding of prophylactics. U. S. v. 246 Gross * * *. (F. D. C. No. 25394. Sample No. 19531–K.)

LIBEL FILED: August 17, 1948, Middle District of Tennessee.

ALLEGED SHIPMENT: On or about July 12, 1948, by World Merchandise Exchange & Trading Co., Inc., from New York, N. Y.

PRODUCT: 246 gross of *prophylactics* at Nashville, Tenn. Examination of samples showed that 6.3 percent were defective in that they contained holes.

LABEL, IN PART: "Silver-Tex Prophylactics Manufactured by The Killian Mfg. Company, Akron, Ohio."

NATURE OF CHARGE: Adulteration, Section 501 (c), the quality of the article fell below that which it purported and was represented to possess.

Misbranding, Section 502 (a), the label statement "Prophylactics" was false and misleading as applied to an article containing holes.

DISPOSITION: December 16, 1948. Default decree of destruction.

2575. Adulteration and misbranding of prophylactics. U. S. v. 94 Gross * * *. (F. D. C. No. 25501. Sample No. 485–K.)

LIBEL FILED: August 25, 1948, Western District of North Carolina.

ALLEGED SHIPMENT: On or about July 9, 1948, by World Merchandise Exchange & Trading Co., Inc., from New York, N. Y.

PRODUCT: 94 gross of *prophylactics* at Charlotte, N. C. Examination of samples showed that 2.8 percent were defective in that they contained holes.

LABEL, IN PART: "Texide Prophylactic Manufactured by L. E. Shunk Latex Prod., Inc., Akron, Ohio."

NATURE OF CHARGE: Adulteration, Section 501 (c), the quality of the article fell below that which it was represented to possess.

Misbranding, Section 502 (a), the label statements "Prophylactics" and "Fine Quality Prophylactic Electronically Tested For Your Protection" were false and misleading as applied to an article containing holes.

DISPOSITION: September 27, 1948. Default decree of condemnation and destruction.

2576. Adulteration and misbranding of prophylactics. U. S. v. 12 Gross * * *. (F. D. C. No. 24494. Sample No. 14692-K.)

LIBEL FILED: April 2, 1948, Northern District of Illinois.

ALLEGED SHIPMENT: On or about October 24, 1947, by the National Hygenics Products, from Akron, Ohio.

PRODUCT: 12 gross of *prophylactics* at Chicago, Ill. Examination of samples showed that 5.56 percent were defective in that they contained holes.

LABEL, IN PART: "Texide Prophylactics Mfd. by L. E. Shunk Latex Products Inc Akron, Ohio."

NATURE OF CHARGE: Adulteration, Section 501 (c), the quality of the article fell below that which it purported or was represented to possess.

Misbranding, Section 502 (a), the label statement "Prophylactic" was false and misleading as applied to an article containing holes.

DISPOSITION: November 18, 1948. Default decree of condemnation and destruction.

2577. Adulteration and misbranding of prophylactics. U. S. v. 25 Gross * * *. (F. D. C. No. 25437. Sample No. 37098-K.)

LIBEL FILED: On or about October 12, 1948, District of Oregon.

ALLEGED SHIPMENT: On or about June 30 and July 8, 1948, by the Rexall Drug Co., from St. Louis, Mo.

PRODUCT: 25 gross of *prophylactics* at Portland, Oreg. Examination of samples showed that 2.77 percent were defective in that they contained holes.

LABEL, IN PART: "Roger (O. K.) Prophylactic Roger Rubber Products, Inc. Los Angeles, Cal."

NATURE OF CHARGE: Adulteration, Section 501 (c), the quality of the article fell below that which it purported and was represented to possess.

Misbranding, Section 502 (a), the label statement "Prophylactic" was false and misleading as applied to an article containing holes.

DISPOSITION: November 5, 1948. Default decree of condemnation and destruction.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF FALSE AND MISLEADING CLAIMS

DRUGS FOR HUMAN USE*

2578. Misbranding of Kaadt Diabetic Treatment. U. S. v. Dr. Charles F. Kaadt (Kaadt Diabetic Institute and Kaadt Diabetic Clinic), Dr. Peter S. Kaadt, and Robert S. Benson. Pleas of not guilty. Tried to the jury. Verdict of guilty. Doctors Charles F. Kaadt and Peter S. Kaadt each sentenced to pay fine of $1,000 and costs and to serve 1 year in prison on each of the seven counts of the indictment, with the sentences on first three counts to run consecutively, those on remaining counts to be suspended, and defendants to be placed on probation when released from prison. Defendant Benson sentenced to pay fine of $350 and to serve one year in prison, with prison sentence to be suspended and defendant to be placed on probation for two years. Judgment affirmed upon appeal. (F. D. C. No. 21454. Sample Nos. 23351-H to 23353-H, incl., 51231-H, 51234-H, 54605-H, 54606-H, 70101-H to 70105-H, incl.)

INDICTMENT RETURNED: On or about January 31, 1948, Northern District of Indiana, against Dr. Charles F. Kaadt, trading as the Kaadt Diabetic Institute and Kaadt Diabetic Clinic, South Whitley, Ind., and against Dr. Peter S. Kaadt, who was associated in the conduct of the business of the institute and clinic, and Robert S. Benson, superintendent.

ALLEGED SHIPMENT: Between February 13, 1945, and March 29, 1946, from the State of Indiana into the States of Missouri, Michigan, Minnesota, and Florida.

PRODUCT: The *Kaadt Diabetic Treatment* consisted of a liquid medicine composed essentially of vinegar, potassium nitrate, protein, and a digestant, and adjunctive medication included pepsin, pancreatin, diastase, a laxative drug, and a solution used to test urine for sugar. The treatment was accompanied by certain labeling, consisting of a booklet designated "Of Great Interest to Diabetics," a leaflet entitled "We do Not prescribe any Set diet," and a form letter addressed to "Dear Friend."

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements in the accompanying labeling of the *Kaadt Diabetic Treatment* were false and misleading. These statements represented and suggested that the product would be efficacious in the cure, mitigation, and treatment of diabetes, whereas it would not be efficacious for such purposes.

DISPOSITION: On February 27, 1948, a motion for dismissal was filed on behalf of the defendants, on the grounds that the indictment did not state facts sufficient to constitute an offense against the United States, and a similar motion was filed on behalf of Dr. Charles Kaadt, on the grounds that the issue as to the efficacy of the treatment was res judicata. In addition, a motion for a bill of particulars was filed. On February 29, 1948, the motions for dismissal were denied. The motion for a bill of particulars was denied also, except for that part requesting information as to how the circulars and leaflets described in count 3 accompanied the treatment. The defendants thereafter entered a plea of not guilty. The case came on for trial before a jury, at the conclusion of which the jury returned a verdict of guilty. Motions for a new trial and arrested judgment were filed on behalf of the defendants and were subsequently

*See also Nos. 2552-2555, 2559, 2560, 2566, 2570-2577.

denied. On May 4, 1948, the court sentenced Doctors Charles F. Kaadt and Peter S. Kaadt, each to pay a fine of $1,000 and costs and to serve one year in prison on each of the seven counts of the indictment, with the sentences on the first 3 counts to run consecutively, those on the remaining counts to be suspended, and the defendants to be placed on probation when released from prison. Defendant Robert S. Benson was sentenced to pay a fine of $350 and to serve one year in prison, with the prison sentence to be suspended and the defendant to be placed on probation for two years, conditioned that he refrain from engaging in a similar business.

An appeal was taken by Doctors Charles F. Kaadt and Peter S. Kaadt to the United States Court of Appeals for the Seventh Circuit, and on December 7, 1948, the following opinion was handed down by that court:

KERNER, *Circuit Judge*: "These are appeals from a judgment sentencing each appellant to a term of imprisonment after a jury had found them guilty as charged in an indictment containing seven counts and alleging violation of the Federal Food, Drug, and Cosmetic Act of June 25, 1938, 52 Stat. 1040, 21 U. S. C. A. § 301 et seq. in that they introduced or delivered for introduction into interstate commerce misbranded drugs.

"Each of the seven counts charged that appellants did, on a date stated, cause to be introduced and delivered for introduction into interstate commerce, consigned to a named individual, an article of drug; that accompanying the drug was certain printed matter; that the statements in the accompanying printed matter were false and misleading because they represented and suggested and created in the mind of the reader the impression that the drug would be efficacious in the cure, mitigation, and treatment of diabetes, whereas in fact and in truth the drug would not be so efficacious.

"The printed matter consisted of (1) a letter signed by C. F. Kaadt, referring to a booklet dealing with his theory of the cause, symptoms, and effect of diabetes and the treatment of same, in which he states: 'I have treated many cases that have been in a very advanced stage * * *. * * * I will be pleased to see you'; (2) a leaflet beginning with the words 'We do Not prescribe any Set diet', and (3) a circular entitled 'Of Great Interest to Diabetics.'

"Section 331 (a) of the Act prohibits the introduction into interstate commerce of any drug that is adulterated or misbranded. It is misbranded according to § 352 (a) if its 'labeling is false or misleading in any particular.' The term labeling is defined in § 321 (m) to mean 'all labels and other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article.' Section 333 (a) makes the violation of any of the provisions of § 301 a misdemeanor.

"Four questions are argued for reversal of the judgment. In substance appellants' contentions are (1) the misbranding, if any, must occur in the labels used, and the labels must accompany the drug into interstate commerce; (2) the representations made in the labeling were honest expressions of their opinion; (3) the court erred in instructing the jury; and (4) the doctrine of *res judicata* was applicable.

"First: Appellants argue that the misbranding must occur in the labels used and the labels must accompany the drug into interstate commerce; that there is nothing in any of the three items of printed matter that informs the patient as to how the medicine is to be used; that the ingredients of the medicine are not given in the literature and no therapeutic claim is made for it, nor does any statement appear that it is efficacious in the treatment of diabetes except as to results had in prior cases.

"The record discloses that all three items of printed matter or literature are not involved in every count. The circular is involved in each count and is the only printed matter in counts 2, 5 and 7. In addition to the circular, counts 1, 3 and 4 involve the leaflet, and counts 4 and 6 involve the letter. The circumstances under which the drug and the literature were introduced or delivered for introduction into interstate commerce varied, but the general pattern was the same. A prospective patient, living outside of Indiana, addressed a letter of inquiry to appellants' clinic and in response received the printed circular and sometimes the form letter. The circular contained the following statements and representations.[1] The patient thereafter attended appellants' clinic, and while there received the leaflet containing diet recommendations which stated in part,[2] and in some instances also received a copy of the circular. Before leaving, the patient had delivered to him, or appellants later shipped to him, a supply of the drug constituting a three-months' treatment. In five of the seven counts (counts 1, 4, 5, 6 and 7) it was alleged that a supply of the drug, other than that received by the patient at the clinic, was shipped from the clinic to the patient. In those counts the shipment of the additional supply of the drug and the accompanying labeling is charged as the violative shipment.

"We have already been told that the phrase 'accompanying such article' is not restricted to labels that are on or in the article or package that is transported, and that the first clause of § 321 (m) clearly embraces advertising or descriptive matter that goes with the package in which the article is transported. The second clause—'accompanying such article'—has no specific reference to packages, containers or their contents, and it plainly includes what is contained within the package whether or not it is 'upon' the article or its wrapper or container, *Kordel* v. *United States*, decided by the United States Supreme Court on November 22, 1948, and the advertising matter need not travel with the drug, *United States* v. *Urbuteit*, decided by the United States Supreme Court on November 22, 1948. And since in our case it appears that the printed matter was used in the sale of the drug, that it advertised and explained the use of the drug, and that the drug and the printed matter moved from Indiana to a point outside of the State of Indiana, we are impelled to hold that the printed matter was 'labeling' within the meaning of the Act.

"Second: Appellants insist that the representations made in the labeling were expressions of opinion that they honestly believed. They assert that

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[1] "3 Months' Medical Treatment to take home with you when you leave the institute * * *

"* * * there is real hope for the diabetic, and the possibility of recovery * * *

"When this hope is presented in the form of a method and a treatment, which is free from prolonged or continuous dieting, with internal medicine taken by mouth, and without the necessity of absence from home, work, or business, it is certain to receive the most eager consideration of every diabetic. This consideration is invited in terms of what actually has been accomplished in a large number of cases of relief and recovery.

* * *

"The Kaadt Diabetic Intitute is the culmination of over thirty years of successful treatment of diabetics by Dr. C. F. Kaadt * * *

* * *

"The principal method of treatment is an internal medicine taken by mouth.

* * *

"In the majority of cases the patient resumes a normal diet within two or three weeks after beginning the treatment.

* * *

"The files of the Institute contain many letters from grateful and appreciative patients expressing their recovery and a return to normal living."

[2] "Accurate dosage is difficult so if you feel that you are not getting along as well as you should increase your dose a little. It may be necessary to double it. On the other hand, if you are taking too much decrease it a little, or put in more water. The amount of water can be decided by the patient as it causes no loss of effectiveness by diluting. Drink plenty of water."

'this is a repeat of the constant quarrel existing in the medical profession as to what is proper and what is improper treatment of disease'; that a difference of judgment among medical men as to the best course or method of treatment does not tend to prove that either party is wholly wrong or wholly right, and that all this case reflects is that certain physicians believe in one course of treatment and other physicians believe in another course of treatment. They make the point that before a court is warranted in submitting the false or misleading qualities of an assertion of effectiveness to a jury to decide, it must be satisfied that something more is involved than mere differences of opinion between schools or practitioners.

"In this case, the issue left to the jury was whether the labeling was false and misleading in that the statements in the printed matter represented and suggested and created in the mind of the reader and led him to believe that the drug was efficacious in the cure, mitigation, or treatment of diabetes. The labeling, as we have already observed, represented that 'there is *real* hope for the diabetic, and the possibility of recovery; * * * this hope is presented in the form of a method and a treatment, which is free from prolonged or continuous dieting * * *. This consideration is invited in terms of what actually had been accomplished in a large number of cases of relief and recovery. * * * In the majority of cases the patient resumes a normal diet within two or three weeks after beginning the treatment.'

"The drug or treatment consisted principally of a mixture of vinegar and potassium nitrate (saltpeter); Taka-diastase, a proprietary digestive preparation, was sometimes added, but analysis revealed no Taka-diastase because it is inactivated and destroyed in a solution as strongly acid as the vinegar medicine. To show the ineffectiveness of the treatment, there was the testimony of patients who had been treated at the clinic and who had subjected themselves to the recommended home treatment with the vinegar medicine, and the testimony of relatives of former patients who had undergone the treatment and subsequently died. Each of these histories was supported by competent medical testimony. A diabetic under competent medical care, taking insulin and on a regulated diet, with his disease under control, was induced to enter the clinic for the prescribed period. In accordance with appellants' recommendations, he decreased his dosage of insulin or discontinued it and substituted appellants' treatment. After subjecting himself to appellants' treatment, he experienced results that commonly follow uncontrolled or improperly treated diabetes. The serious and irreparable injuries that followed included diabetic coma, permanent eye injuries, and gangrene resulting in amputation.

"Outstanding medical authorities who were specialists in the treatment of diabetes, testified that the treatment used and recommended by appellants would have no effect in the treatment of diabetes; that it was worthless and absolutely of no value. These experts testified that the opinions expressed by them represented the consensus of medical opinion of the authorities on diabetes; that insulin was the only drug known to be effective in the treatment of diabetes; that a proper diet and exercise must be integrated with the dosage of insulin; and that the patient must be educated to look after his condition.

"We have already held that a consensus of medical opinion is a question of fact and provable as such, *United States* v. *Dr. David Roberts Veterinary Co.*, 104 F. 2d 785, and it has been held that a conflict of medical opinion concerning the effectiveness of a drug also presents a question of fact, *Seven*

Cases v. *United States*, 239 U. S. 510, and since it is not necessary in a prosecution under the Act to prove guilty knowledge or wrongful intent, *United States* v. *Dotterweich*, 320 U. S. 277; *United States* v. *Parfait Powder Puff Co.*, 163 F. 2d 1008; and *United States* v. *Greenbaum*, 138 F. 2d 437, we think the jury's finding that the labeling was false and misleading was supported by substantial evidence.

"Third: It is argued that under an instruction given the jury, the jury might return a verdict of guilty on all counts even though the unlawful distribution was entirely intrastate.

"In determining whether there is error in the court's instructions the charge must be viewed as a whole, *United States* v. *Carruthers*, 152 F. 2d 512; and *United States* v. *Fleener*, 162 F. 2d 935. The trial judge in the instant case, in an endeavor to guide the jury in its determination of whether any or all of the defendants shared the required responsibility in the conduct of the business, told the members of the jury that if they found that any or all of the defendants shared responsibility in conducting the business and that the operation of that business resulted in unlawful distribution of misbranded drugs, the defendants who shared such responsibility might be found guilty. He also instructed the jury that the burden of proof was upon the Government to prove every material allegation of the indictment and to establish the defendants guilty beyond a reasonable doubt, and that in determining whether the defendants did have a responsible share in the conduct of the business, it must take into consideration the work that each defendant did at the Kaadt Diabetic Clinic or Institute, the duties and responsibilities of each, and the extent to which each controlled or directed the conduct of the business.

"It is true, appellee did not show that in each instance all of the defendants physically participated in introducing the misbranded drug into interstate commerce. But physical participation is not necessary in order to have criminal responsibility attach for a violation of the Act. *United States* v. *Dotterweich*, *supra*, 284, 285, and *United States* v. *Parfait Powder Puff Co.*, *supra*.

"Appellants also complain of the form of the verdicts. It is claimed the court failed to instruct the jury that defendants could be found guilty on some counts and not guilty on others. And they complain of an instruction which told the jury that the Government need not prove that all of the statements in the labeling were false or misleading, and that if the jury found that any one of the claims or statements in the labeling was false or misleading it might find that the drugs in question were misbranded. The criticism heaped upon the instruction is that all three items of printed matter were not involved in each of the counts, and that in deliberating on a particular count, the jury might have considered items of printed matter not involved in that count. But the court also told the jury that it might consider each separate item, and in the counts where more than one piece of printed matter was involved, it might consider the effect of the combined influence of all types of printed matter involved.

"The record discloses that no objection was taken to the form of the verdicts or to the giving of this instruction. In this state of the record, under Rule 30 of the Federal Rules of Criminal Procedure, 18 U. S. C. A. foll. § 687, appellants are precluded from a review. We have, however, considered the points raised. We think the trial judge made it clear to the jury that each defendant could be found either guilty or not guilty on each of the counts, and that it was told that in weighing the evidence in a particular count it should consider only the

items of printed matter involved in that count. There was no error committed by the court in instructing the jury.

"Fourth: Appellant Charles F. Kaadt contends that the court erred in refusing to invoke the doctrine of *res judicata*.

"To be sure, the doctrine of *res judicata* is applicable to criminal as well as civil proceedings, and operates to conclude those matters in issue which have been determined by a previous verdict, even though the offenses be different. *Scalfon* v. *United States*, 332 U. S. 575. In our case it appears that during the trial Kaadt offered in evidence the verdict of a jury and the opinion of the District Court in 1940 in the case of the *United States* v. *Charles F. Kaadt*, 31 F. Supp. 546. The indictment in that case charged him with a scheme to defraud and the use of the mails to further such a scheme. He asserts that the question and issue passed upon in the prior action dealt with the therapeutic value of his medicine, and argues that that issue can not again be litigated in this case. He should not be vexed more than once for the same cause. In support of his argument he cites, among other cases, *United States* v. *Oppenheimer*, 242 U. S. 85; *Oklahoma* v. *Texas*, 256 U. S. 70; and *Tait* v. *Western Maryland Railway Co.*, 289 U. S. 620.

"Counsel for appellee concedes, as he must, the propriety of invoking *res judicata* when the issues have previously been tried and determined, but to avoid the application of the doctrine, he points to the fact that in a scheme to defraud the significant fact is the intent and purpose, and that the two essential elements of the offense of using the mails to defraud (18 U. S. C. A. § 338) are the existence of a scheme to defraud and the placing or causing to be placed in the post office a letter, post card, package, writing, circular, pamphlet, or advertisement, for the purpose of executing the scheme. *Fournier* v. *United States*, 58 F. 2d 3; *United States* v. *Lowe*, 115 F. 2d 596; and *United States* v. *Cohen*, 145 F. 2d 82.

"We agree with appellee that it is impossible from this record to ascertain on what ground the jury acquitted Kaadt of the offense of using the mails to defraud. But the instant prosecution does not involve any question of fraud. The misbranding charged is based on § 352 (a) of the Act which provides that a drug or device shall be deemed to be misbranded if its labeling is false or misleading in any particular. And *Sealfon* v. *United States*, *supra*, is of no aid to appellant for the reason that in the unique circumstances of that case, the jury's verdict in the conspiracy trial was a determination favorable to Sealfon of the facts essential to a conviction of the substantive offense. Appellee in the present case was not required to prove intent to defraud. Thus the offense of using the mails to defraud and the offense of introducing or delivering for introduction into interstate commerce misbranded drugs are not the same, and hence there is no *res judicata*. Compare *United States* v. *Five cases*, 156 F. 2d 493.

"The judgment of the District Court is affirmed."

2579. Misbranding of Adolphus vitamin and mineral products. U. S. v. Adolphus Hohensee. Plea of not guilty. Tried to the jury. Verdict of not guilty on count 1; verdict of guilty on remaining counts. Fine $1,800. (F. D. C. No. 20125. Sample Nos. 31973–H to 31983–H, incl.)

INFORMATION FILED: September 25, 1946, District of Arizona, against Adolphus Hohensee, of Scranton, Pa., and Phoenix, Ariz.

ALLEGED SHIPMENT: On or about April 2, 1945, from the State of Arizona into the State of California.

LABEL, IN PART: "Malt-O-Soy (Soy Milk) Ingredients Soya Beans, Vegetable Oils, Raw Sugar, Dextrose, Sodium Chloride, Calcium Phosphate, Diabasic Salt"; "Improved 'B' Complex A Food Supplement * * * Each Tablet Contains Not Less Than Vitamin B_1—750 USP Units (2.27 mg.); Vitamin B_2 (G)—2,000 Micrograms (2.0 mg.); Vitamin B_6—250 Micrograms (.25 mg.); Niacinimide—20,000 Micrograms (20.0 mg.); Calcium Pantothenate—1,000 Micrograms (1.0 mg.)"; "High Potency Vitamin C 250 Mgs. A Food Supplement Each Tablet Contains: 5,000 USP Units (250 Mgs.) of Vitamin C (Ascorbic Acid)"; "Dicalcium Phosphate and Vitamin D A Food Supplement Each Tablet Contains Dicalcium Phosphate and Vitamin D (Irradiated Ergosterol) and Represents 210 Mgs. Calcium, 150 Mgs. Phosphorus and 400 USP Units Vitamin D"; "Garlic Parsley Each Capsule Contains Approximately 2500 Mgs. of Clean Fresh Parsley and Peeled Garlic"; "Food Supplement Mineral Capsules The Following Weights Apply to the Mineral Salts (Iron) from Ferrous Sulphate Dried 56.1 Mg. (Calcium) from DiCalcium Phosphate Anhyd. 187.0 Mg. (Phosphorous) from No. 2 42.6 Mg. (Iodine) from Potassium Iodide .15 Mg. (Magnesium) from Magnesium Sulphate Dried 7.2 Mg. (Zinc) from Zinc Sulphate C. P. Dried 3.0 Mg. (Copper) from Copper Sulphate Anhyd. 5.0 Mg. (Sodium) from Sodium Chloride C. P. Dried 2.5 Mg. (Cobalt) from Cobalt Sulphate .2 Mg. (Potassium) from Potassium Chloride C. P. 1.3 Mg. (Manganese) from Manganous Sulphate ($2H^2O$) 3.4 Mg. (Sulphur) traces from Nos. 1, 6, 7, 9 and 11 Liver Concentrate, from Fresh Livers 30.0 Mg. Soybean Lecithin 15.0 Mg. C. P. Wheat Germ Oil 214.0 Mg."; "Vitamin C 30 Mg. A Food Supplement Each Tablet Contains 600 U.S.P. Units (30 Mg.) Vitamin C (Ascorbic Acid)"; "Pure Soy Bean Lecithin and Vitamin D A Food Supplement Each Capsule Contains 4 Gr. Soybean Lecithin in 3 Minim Soybean Oil with 150 USP Units Vitamin D from Irradiated Ergosterol"; "3 Minim Capsules * * * Containing Pure, Virgin Cold Pressed Wheat Germ Oil A Rich Natural Source of Vitamin E."

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements in the labeling were false and misleading since the articles would not be effective to accomplish the purposes represented and suggested. These statements were set forth on the labels of the articles, in accompanying display cards entitled "The Wheel O'Life," and in accompanying booklets entitled "Lecture Series on Health and Progress Better Eyes Without Glasses," "Lecture Series on Health and Progress How to Think and Attain Success," "The Health, Success and Happiness Lectures," "* * * 'High Blood Pressure' * * * Degenerative Diseases," "What About the Vegetables and Fruits We Eat Today?" "Lecture Series on Health and Progress * * * What is Brain Food," and "Lecture Series on Health and Progress Your Personality Glands."

The false and misleading statements in the labeling represented and suggested:

That the *Malt-O-Soy* would be of value in treating arthritis and in correcting acid or ulcer states; that it would serve as an ideal nonresidue diet of high nutritional value in dysentery, sprue, and colitis; that it would supply every purpose of animal milk for the growing child, for the adult, and for the pregnant or nursing mother; and that it was hypoallergic.

That the *Improved "B" Complex Tablets* would be an adequate treatment for colds and sinus conditions; that it would be efficacious in the prevention of colds, sinus conditions, allergy, and marked acidosis; that it would enable one to attain good eyesight without glasses; that it would correct farsightedness, nearsightedness, middle-age sight, and inflamed eyes; that it would be an

adequate treatment for asthma and hay fever; that it would aid heart action, nerves, and blood formation; and that when taken alone or in combination with all the vitamins and minerals and an 80 percent alkaline diet, it would insure good eyesight, healthy sinuses, and vigorous lungs.

That the *High Potency Vitamin C Tablets*, when taken alone or in conjunction with the other measures indicated in the labeling, would be adequate treatment for colds and sinus conditions; that it would prevent colds, sinus conditions, and allergy; that it would correct marked acidosis, constipation, and digestive disturbances; that it would build up resistance; that it would make the eyes beautiful; that it would minerally balance the blood stream; that it would enable one to attain good eyesight without glasses; that it would prevent many children's diseases; that it would correct farsightedness, middle-age sight, nearsightedness, astigmatism, and inflamed eyes; and that it would insure healthy sinuses and vigorous lungs.

That the *Dicalcium Phosphate and Vitamin D Tablets* would be effective in correcting disease of the brain cells; that it would prevent and correct brain destruction; that it would develop brain cells; that it would supply mental power; that it would promote will-power and mentality; and that it would steady the nerves.

That the *Garlic Parsley Capsules* would be efficacious in the treatment of high blood pressure, headache, ear noises, rushing of the blood to the head, heart palpitation, general weakness, and debility; that it would open arteries which have become smaller and would supply flexibility to stiff and hardened arteries; that it would loosen and dissolve incrustation on the walls of the arteries; that it would be efficacious in the cure and prevention of high blood pressure; that it would bring about a profound cleansing effect upon the intestines and blood stream; that it was an internal antiseptic and blood purifier; that it would be of benefit in the treatment and prevention of influenza, rheumatism, and chronic catarrh; that it would inhibit the growth of the tubercle bacillus; that it would be efficacious in the cure, mitigation, treatment, and prevention of tuberculosis of the skin, bones, glands, lungs, and special parts of the body; and that it would strengthen the circulatory system.

That the *Food Supplement Mineral Capsules* would be an adequate treatment for rickets, bony deformities, bad teeth, nervous disorders, reduced resistance to other diseases, fatigability, behavior disturbances such as incorrigibility, assaultiveness, and nonadaptability, infections of the nose and throat, swollen glands, enlarged and diseased tonsils, defective vision, round shoulders, bow legs, and anemia; that it would build up resistance and, when used alone or in combination with vitamins A, B, and C, and an 80 percent alkaline diet, would prevent colds and sinus conditions; that it would correct acidosis, digestive disturbance, sour stomach, and constipation; that it would make the eyes beautiful; that it would enable one to attain good eyesight without glasses; that it would prevent and correct children's diseases, farsightedness, middle-age sight, nearsightedness, astigmatism, inflamed eyes, asthma, and hay fever; that it would insure good nerves; that it would maintain the intestinal tract free of toxemia; and that it would provide good eyesight, healthy sinuses, and vigorous lungs.

That the *Vitamin C Tablets*, when taken alone or in conjunction with the other measures indicated in the labeling, would be an adequate treatment for colds and sinus conditions; that it would prevent colds, sinus conditions, and allergy; that it would correct marked acidosis, constipation, and digestive disturbances; that it would build up resistance; that it would make the eyes

beautiful; that it would minerally balance the blood stream; that it would enable one to attain good eyesight without glasses; that it would prevent children's diseases; that it would correct farsightedness, middle-age sight, nearsightedness, astigmatism, and inflamed eyes; and that it would insure healthy sinuses and vigorous lungs.

That the *Pure Soy Bean Lecithin and Vitamin D Capsules* would be of value as a brain food; that it possessed special virtues for the treatment of rickets, dyspepsia, diabetes, anemia, and tuberculosis; that it was especially required by the stomach, kidneys, liver, lungs, and pancreas; that it would be efficacious in the correction in an undernourished person of despondency, early discouragement, and lack of will-power and enthusiasm; that it would provide proper reasoning power; that it would restore loss of memory; that it would correct lack of power to concentrate and lack of coordination between the brain and muscles; that it would be efficacious in the correction of an inferiority complex; that it would increase mental efficiency; and that it would produce healthy physical and mental developments and glandular functioning in children.

That the *Wheat Germ Oil Capsules* would be of benefit to women during the menopause; that it would supply proper nourishment to all important glands including the sex glands; that it would be efficacious in the correction of nervous irritability, flashes before the eyes, fever, chills, and heat spells; that it would be efficacious in the correction in men of difficult urination, pelvic pains, cramps, prostate gland trouble, and loss of the sexual fluid; that it would supply pep and life; that it would benefit every fiber of the muscles in his body as well as the valves that control the various fluids; that it would be efficacious in the prevention of gland atrophy; that it would lengthen life; that it would permit living a life free from suffering and disease; that it would promote general well-being, vigor of personality, glands, and mental and physical vigor; and that it was essential to nerve and muscle tissue, for maximum growth and nutrition, and for pregnant women.

The information charged further that, with the exception of the *Garlic Parsley Capsules*, the above products and a shipment of *Concentrated Broth* were misbranded under the provisions of the law applicable to foods, as reported in notices of judgment on foods.

DISPOSITION: A plea of not guilty having been entered, the case came on for trial before a jury on February 17, 1948. The trial ended on February 20, 1948, with the return by the jury of a verdict of not guilty on the count which related to the *Concentrated Broth* and a verdict of guilty on all other counts of the information. The court imposed a fine of $1,800 on March 8, 1948. On the same day, the court denied the defendant's motion for a new trial and arrest of judgment.

2580. Misbranding of Gotu Kola tablets, Minerals Plus tablets, sarsaparilla root, Cetabs tablets, Fenugreek tea, Fero-B-Plex tablets, Bolax tablets, Ormotabs tablets, Ribotabs tablets, Kordel tablets, Everm wheat germ oil capsules, Kordel-A capsules, Garlic Plus tablets, Niamin tablets, and sarsaparilla tea. Three Informations: U. S. v. Laura Kordel (Gotu Kola Distributors) and Lelord Kordel, U. S. v. Lelord Kordel (Lelord Kordel Products), and U. S. v. Lelord Kordel (Lelord Kordel Products and Nutrition Enterprises). Pleas of not guilty. Tried to the court. Verdict of guilty against Lelord Kordel; verdict of not guilty

against Laura Kordel. Fine of $4,000 against Lelord Kordel. Judgment affirmed upon appeal to U. S. Court of Appeals for the Seventh Circuit and upon appeal to U. S. Supreme Court. (F. D. C. Nos. 14307, 14308, 17777. Sample Nos. 49028–F, 70727–F, 70767–F to 70771–F, incl., 28363–H to 28371–H, incl., 28373–H, 28375–H, 28376–H, 29408–H.)

INFORMATIONS FILED: On July 11 and 13, 1945, and January 21, 1946, in the Northern District of Illinois, against Laura Kordel, trading as Gotu Kola Distributors, at Chicago, Ill., and Lelord Kordel, and against Lelord Kordel, trading as Lelord Kordel Products and Nutrition Enterprises, at Chicago, Ill.

ALLEGED SHIPMENT: Between the approximate dates of July 10, 1942, and February 28, 1945, from the State of Illinois into the States of Ohio, Washington, and California. It was alleged that the *Gotu Kola tablets* were shipped by Laura and Lelord Kordel and that the other products were shipped by Lelord Kordel.

PRODUCT: Analyses disclosed that the *Gotu Kola tablets* consisted of white sugar- and lime carbonate-coated tablets containing, chiefly, pennywort, iron sulfate, calcium sulfate, and talc; that the *Ferro-B-Plex tablets* consisted of calcium carbonate-coated tablets containing vitamins B_1 and B_2 and niacin, and 273 milligrams of calcium per 3 tablets, 66 milligrams of iron per 3 tablets, and 158 milligrams of phosphorus per 3 tablets; that the *Minerals Plus tablets* consisted of gray compressed tablets containing per 6 tablets approximately 687 milligrams of calcium, 579 milligrams of phosphorus, and 81.6 milligrams of iron, together with a small amount of iodine, vitamin D, and chlorophyll; that the *sarsaparilla root* consisted of a coarsely cut plant mixture consisting principally of sarsaparilla root with a small amount of sassafras bark; that the *Cetabs tablets* consisted of coated tablets containing 31 milligrams of ascorbic acid per tablet; that the *fenugreek tea* consisted essentially of whole fenugreek seeds with some whole barley seeds and other whole unidentified seeds; that the *Bolax tablets* were brown compressed tablets consisting essentially of powdered plant material, including the emodin bearing drugs, senna and buckthorn; that the *Ormotabs tablets* were sugar-coated tablets consisting essentially of plant material, including sassafras, chlorophyll, and an iodine bearing substance; that the *Ribotabs tablets* were compressed tablets containing riboflavin; that the *Kordel tablets* consisted essentially of sodium citrate, plant material, and oil of wintergreen; that the *Everm wheat germ oil capsules* were gelatin capsules containing an oil-like wheat germ oil; that the *Kordel-A capsules* were gelatin capsules containing a vitamin-A-bearing oil; that the *Garlic-Plus tablets* consisted essentially of dried plant material, including garlic; that the *Niamin tablets* were coated tablets containing 10 milligrams of niacinamide and a small amount of yeast; and that the *sarsaparilla tea* consisted essentially of a mixture of sarsaparilla root and sassafras bark.

NATURE OF CHARGE: *Gotu Kola tablets.* Misbranding, Section 502 (a), certain statements in a circular accompanying the article were false and misleading. These statements represented and suggested that *Hydrocotyle asiatica*, the common or usual name of which is Indian Pennywort, is a rich, natural, seemingly secret source of dynamic energy; that the article would be effective in producing marvelous physique and full, vibrant physical existence; that it would be effective in prolonging life, perpetuating and restoring youth, and increasing vitality; that it would have an energizing effect on the cells of the brain and would preserve it indefinitely; that it would be effective in strengthening and revitalizing worn-out bodies and brains, prevent brainfag and nervous

breakdowns, keep old age away, and prolong the existence of the brain; that it would be effective in producing energy, a perfect physical life, more abundant power, more perfect living, and a fuller, richer physical existence; that it would generally enhance physical life and manifest a brighter, keener, mental activity, a restimulated ambition, and a renewed optimistic outlook; that it would be effective in the treatment of those below par physically and mentally; that it would be effective in producing erect posture, sharp eyes, velvety skin, limbs of splendid proportion, deep chests, firm bodies, gracefully curved hips, flat abdomens, rhythm of motion, gracefulness and poise, stately bearing, intelligence of eyes, pleasing laughter, and extraordinary physique; and that the article would be effective in the treatment of rheumatism, neuritis, and nervous breakdown. The drug *Hydrocotyle asiatica* is not a rich, natural, seemingly secret source of dynamic energy, and the article would not be effective for the purposes represented.

Cetabs tablets, Ormotabs tablets, Ribotabs tablets, Fero-B-Plex tablets, Minerals Plus tablets, Bolax tablets, Kordel tablets, Everm wheat germ oil capsules, Kordel-A capsules, fenugreek tea, Garlic Plus tablets, and Niamin tablets. Misbranding, Section 502 (a), certain statements and designs in the bulletins and booklets and on the placard accompanying these articles were false and misleading. The statements and designs represented and suggested:

That the *Cetabs tablets* would be effective to insure strong teeth, healthy gums, good digestion, clear complexion, and vigorous health; and that it would be effective to prevent and correct premature old age, liver troubles, stiff joints, hormone deficiency and malfunction, diabetes, poor complexion, fatigue, heart trouble, colds, high blood pressure, pyorrhea, loss of weight, tooth decay retarded growth, and poor appetite.

That the *Ormotabs tablets* would be effective in the treatment of anemias, internal infections, peritonitis, brain ulcer, osteomyelitis, ulcerated varicose veins, respiratory infections, arteriosclerosis, cardiac hypertension or other heart ailments, nervous fatigue, tubercular infections, and undernourishment in children; that it would be effective to promote hormone production; and that it would provide substances possessing hormone activity.

That the *Ribotabs tablets* would be effective in the treatment and prevention of blindness, high blood pressure, ulcer, loss of weight, oily skin, falling hair, digestive disturbances, and poor complexion.

That the *Fero-B-Plex tablets* would be effective to correct lack of vitality, poor appetite, indigestion, constipation, nervousness, and irritability.

That the *Minerals Plus tablets* would be effective in the treatment and prevention of poor memory, ulceration, bad teeth, general weakness, impaired respiration, fatigue, obesity, liver disorders, stiff joints, nervous breakdown, tonsillitis, rheumatic conditions, impaired glandular function, constipation, and abnormal body cell growth.

That the *Bolax tablets* would be effective in the treatment of acidosis, colds, lack of appetite, and constipation.

That the *Kordel tablets* would be effective in the treatment of arthritis, rheumatism, sciatica, neuralgia, lumbago, and aching joints and muscles.

That the *Everm wheat germ oil capsules* would be effective in the treatment and prevention of heart failure, paralysis, muscular diseases, mental disorders, impotency, reproductive disorders, and infertility.

That the *Kordel-A capsules* would be effective in the cure, mitigation, treatment, and prevention of failing eyesight, red and swollen eyelids, squinting of eyes, color blindness, and acne and other skin disorders.

That the *fenugreek tea* would be effective in the treatment and prevention of stomach upsets, sour taste in the mouth, gas pains, heartburn, hyperacidity, belching, bloating, liver disorders, rheumatic and neuritic pains, debility, ulcers, colitis, internal inflammations, and acidosis.

That the *Garlic Plus tablets* would be effective in the treatment of high blood pressure, headaches, dizziness, shortness of breath, heart pains, sleeplessness, and inability to concentrate.

That the *Niamin tablets* would be effective in the treatment of heart ailments, angina pectoris, cerebral thrombosis, headaches, dizziness, ringing in the ears, deafness, allergies, high blood pressure, nervousness, poor appetite, irritability, kidney disorders, and fatigue.

Further misbranding, Section 502 (a), certain statements in the booklet accompanying the *sarsaparilla root*, *Minerals Plus tablets*, *Fero-B-Plex tablets*, *Bolax tablets*, *fenugreek tea*, *Cetabs tablets*, and *sarsaparilla tea* were false and misleading. These statements represented and suggested that the articles, when taken alone or in combination with each other or with the diets recommended in the booklet, would be effective in the cure, mitigation, treatment, and prevention of arthritis. The articles, when taken alone or in combination with each other or with the recommended diets, would not be effective for such purposes.

Further misbranding, Section 502 (a), certain statements on the label of the *Ormotabs tablets* were false and misleading. These statements represented and suggested that sarsaparilla root, sassafras bark, papain, and chlorophyll are nutritional factors and are of dietary importance. Such substances are not nutritional factors, nor are they of dietary importance.

Further misbranding, Section 502 (a), certain statements on the label of the *Minerals Plus tablets* were misleading. These statements represented and suggested that the tablets were of nutritional significance by reason of the presence of the minerals, magnesium, cobalt, sodium, sulfur, potassium, chlorine, manganese, zinc, nickel, lithium, boron, strontium, silicon, and bismuth. The tablets were of no nutritional significance by reason of the presence of those minerals.

Further misbranding, Section 502 (a), certain statements on the label of the *Kordel tablets* were false and misleading. These statements represented and suggested that the tablets were a food adjunct and would provide ingredients of nutritional significance. The tablets were not a food adjunct and would provide no ingredients of nutritional significance.

Further misbranding, Section 502 (a), certain statements on the label of the *Everm wheat germ oil capsules* were misleading. These statements represented and suggested that there were definite disease conditions in man recognized as due to a vitamin E deficiency in which the capsules would be an effective treatment.

Further misbranding, Section 502 (a), certain statement in the bulletin accompanying the *Kordel-A capsules* were false and misleading. These statements represented and suggested that defective eyes in infants are frequently due to inadequate intake of vitamin A by the mothers. Defective eyes in infants are not frequently due to the condition represented.

DISPOSITION: Pleas of not guilty having been entered, the cases were consolidated for trial before the court. The trial commenced on March 18, 1946, and at its conclusion the court accorded the parties the opportunity to submit briefs. After consideration of all the evidence and the briefs of the parties, the court on June 26, 1946, handed down the following opinion:

LA BUY, *District Judge:* "There are three informations, comprising twenty counts, brought against Laura Kordel and Lelord Kordel for violation of the Federal Food, Drug and Cosmetic Act, 21 U. S. C. A. § 301 et seq., by misbranding. A stipulation between Lelord Kordel trading as Gotu Kola Distributors and as Lelord Kordel Products, and as Lelord Kordel Products and Nutrition Enterprises, has been filed wherein the facts contained in the three informations are agreed. This stipulation is not made by Laura Kordel and is not to be construed as admissions by her.

"With the stipulation of facts as stated in the informations, the only question tried by the court was whether the violation has been proved by the evidence.

"The main contention of defendants' counsel is that since the booklets did not, in a number of counts, physically accompany the drugs they did not therefor 'accompany' the drug within the meaning of Section 321 (m) of the Act. Defendants' counsel urges a strict construction of the word 'accompany' since this is a criminal action and that the penal provisions of the Federal Food, Drug and Cosmetic Act be strictly construed.

"[1–2] It is necessary first to determine the nature of the statute before us. The United States Supreme Court in the case of United States v. Dotterweich, 1943 320 U. S. 277, 64 S. Ct. 134, 136, 88 L. Ed. 48, said: 'The purposes of this legislation thus touch phases of the lives and health of people which, in the circumstances of modern industrialism, are largely beyond self-protection. Regard for these purposes should infuse construction of the legislation if it is to be treated as a working instrument of government and not merely as a collection of English words.' Also in United States v. Antikamnia Co., 1914, 231 U. S. 654, 34 S. Ct. 222, 58 L. Ed. 419, and United States v. Schider, 1917, 246 U. S. 519, 38 S. Ct. 369, 370, 62 L. Ed. 863: 'The purpose of the act is to secure the purity of food and drugs and to inform purchasers of what they are buying. Its provisions are directed to that purpose and must be construed to effect it.'

"It is apparent, therefore, that the purpose of the law is the ever-insistent consideration in its interpretation. Congress by enacting it intended to promote honesty and fair dealing in trade and secure to the public pure and wholesome food and drugs and there must be a reasonable construction to carry out the intention of Congress. This being 'remedial legislation,' the rule of liberal construction is to be followed irrespective of its penal provisions.

"Mr. Justice Story in Taylor et al. v. United States, 1845, 3 How. 197, 11 L. Ed. 559, stated this principle as follows: 'In one sense, every law imposing a penalty or forfeiture may be deemed a penal law; in another sense, such laws are often deemed, and truly deserve to be called remedial.' The judge was, therefore, strictly accurate, when he stated that 'It must not be understood that every law which imposes a penalty is, therefore, legally speaking, a penal law, that is, a law which is to be construed with great strictness in favor of the defendant. Laws enacted for the prevention of fraud, for the suppression of a public wrong, or to effect a public good, are not, in the strict sense, penal acts, although they may inflict a penalty for violating them.' And he added, 'It is in this light I view the revenue laws, and I would construe them so as most effectually to accomplish the intention of the legislature in passing them.' The same distinction will be found recognized in the elementary writers, as, for example, in Blackstone's Commentaries

* * * and Bacon's Abridgement * * * and Comyns' Digest * * * and it is also abundantly supported by the authorities.

"[3] The word 'accompany' has been defined in a number of cases. See United States v. Lee, 7 Cir., 1942, 131 F. 2d 464, 143 A. L. R. 1451; United States v. Research Laboratories, Inc., 9 Cir., 1942, 126 F. 2d 42, certiorari denied 317 U. S. 656, 63 S. Ct. 54, 87 L. Ed. 528; United States v. 7 Jugs, etc., Dr. Salsbury's Rakos, D. C. Minn., 1944, 53 F. Supp. 746, 755. An excellent analysis was made by District Judge Joyce in the Rakos case supra. He said:

The word "accompany," as used in Section 201 (m) (2) was said in United States v. Lee, 7 Cir., 1942, 131 F. 2d 464, 466, 143 A. L. R. 1451, to mean: "The word 'accompany' is not defined in the Act, but we observe that among the meanings attributed to the word are 'to go along with,' 'to go with or attend as a companion or associate,' and 'to occur in association with,' Webster's New International Dictionary, 2d Ed." Naturally, the meanings of accompany will vary in connection with subject matter. "Accompany" as used in this Act is used to describe a relationship between an article of drug and its labeling. Since there "can be no question that among the usual characteristics of labeling is that of informing a purchaser of the uses of an article to which the labeling relates" (United States v. Lee, 131 F. 2d at page 466), the booklets here involved should be scrutinized from this viewpoint. * * *

The stipulation clearly shows that the printed matter and the drugs had a common origin. They had a common destination in that both were intended to come together in the stores of dealers in Achilles' territory. They were interlocking units of a distributional scheme the objective of which was ultimate association and distribution together. There was actual, physical association together in the stores of dealers and actual distribution together in connection with purchases by farmers. It is fair to conclude that these booklets were prepared, shipped and distributed to dealers with the ultimate expectation and intention on the part of the Laboratories that they would serve the purpose of labeling for the three articles of merchandise here involved. Without the booklets, the products themselves lacked labeling, at least in so far as informing purchasers of the purposes and uses of the remedies. The mere fact that the products were shipped at different times, over a different route and were received at a different time from the booklets should not be permitted to confuse or obscure the substance of the matter. * * *

What is vital are such factors as interdependence of the drug and the booklets, common origin, common destination, display, distribution and use together. These determine whether there has been that degree of accompaniment which provides the necessary "misbranded" status under Section 304 (a) [21 U. S. C. A. § 334 (a)]. The mere fortuitous circumstance of an absence of physical association between the booklets and drugs during the interstate journey of the drugs does not in my opinion control.

"[4, 5] It is contended by defendant that the above cited cases were brought under libels of information for the condemnation of the articles involved; that these were civil proceedings; that the present case involves the criminal aspects of the statute and the definition should therefore be differently construed. To adhere to defendant's construction would result in a strange situation wherein under the same statute and the same section, a single word would have a different meaning dependent only on the nature of the action brought. This interpretation would defeat the enforcement of the statute and the court cannot subscribe to such a proposition. Furthermore, the element of forfeiture in a statute is as much a penal provision as is the one imposing a penalty.

"[6] These booklets were shipped by the defendant. The drugs and booklets were sent to the same consignee. They were 'displayed' and were intended to be distributed in relation to the drug. The booklets, pamphlets, or circulars were false and misleading.

"From the evidence and proof in the trial of this case, the court finds the defendant Lelord Kordel guilty of violating the misbranding provisions of the Act. As to the defendant, Laura Kordel, the court is of the opinion the evidence is insufficient to support a conviction and she is therefore discharged."

On the same date, the court fined Lelord Kordel $200 on each count in the informations, a total fine of $4,000, plus costs. An appeal was thereupon taken by Lelord Kordel to the United States Court of Appeals for the Seventh Circuit, and on November 6, 1947, the following opinion was handed down by that court:

SPARKS, *Circuit Judge:* "Appellant was charged by three criminal informations with violation of the Federal Food, Drug and Cosmetic Act, 21 U. S. C. A. sections 301, *et seq.* He waived jury trial and, upon trial by the court, was found guilty and fined $200 on each of the twenty counts contained in the three informations. The appeal is from those judgments.

"The facts as to the shipping of the drugs and the literature alleged to constitute the misbranding charged in the informations were entirely stipulated. Error is asserted in the court's finding that that literature 'accompanied' the drugs in interstate commerce in the purview of the Act prohibiting the introduction or delivery for introduction of any drug that is misbranded. Other contested issues relate to the degree of proof necessary in a criminal proceeding under the Act, whether the Act should be strictly construed, and whether prosecution should have been by indictment rather than by information.

"Appellant is a self-styled authority on nutrition and vitamins. He testified that he had written many papers on the subject of vitamins, herbs, minerals and nutritional diet subjects in general, securing the material for preparation of his papers from books. Operating under various trade names, he had been producing and marketing his own products since January 1941, largely through 'health food' stores. The products appear to be, for the most part, compounded of various vitamins, minerals, and herbs. No charge of falsehood is made as to the principal labels printed on the packages in which each is contained. These labels give the name of the article and distributor, content, recommended dosage, and, in some cases, the alleged daily minimum requirement of the vitamins or minerals therein. Otherwise they give no indication as to their intended uses.[1] The misbranding charged is contained in a number of printed pamphlets and circulars, and one display placard. The modes of distribution of this literature differed as charged in the various counts of the informations. In some cases it was contained in the carton in which the articles were shipped. More often, it was separately shipped to the same consignees, and, in at least one case, a period of a year and a half intervened between the shipment of the product and the literature, respectively.

"Section 301 of the Food and Drugs Act as amended in 1938, 21 U. S. C. A. sec. 331, prohibits the introduction or delivery for introduction into interstate commerce of any drug that is misbranded; section 502, 21 U. S. C. A. sec. 352, provides that a drug shall be deemed to be misbranded if its labeling is false or misleading in any particular; and section 201 (m), 21 U. S. C. A. sec. 321 (m), defines the term 'labeling' to include all labels and other written, printed, or graphic matter '(1) upon any article or any of its containers or wrappers, or (2) accompanying such article.'

[1] The articles involved in the three informations are named "Gotu Kola," "Minerals plus Chlorophyll and Vitamin D," "Cetabs," "Fenugreek Tea," "Fero-B-Plex," "Bolax," "Ormotabs," "Ribotabs," "Kordel Tablets," "Everm," "Kordel A," "Garlic Plus," "Niamin," and "Sarsaparilla Tea."

"It is now generally held that in order to support a misbranding charge under the Act as amended and revised in 1938, it is not necessary that the matter alleged to accompany the product be shipped in the same container (*United States* v. *Research Laboratories*, 126 F. 2d 42), nor even that it be shipped simultaneously (*United States* v. *Lee*, 131 F. 2d 464; *United States* v. 7 *Jugs* ** *Rakos*, 53 Fed. Supp. 746; *United States* v. *Paddock*, 67 Fed. Supp. 819).

"Appellant contends that the cases referred to are not applicable for the reason that all involved civil proceedings rather than criminal, and further, that the literature here involved was not only not shipped in the same carton with the products in all cases, but neither was it intended by him that product and literature should be placed together by the dealer to whom they were sent. His theory apparently is that the matter was not intended for labeling, but for advertising. He points to the fact that all of the printed matter was intended either to be mailed out or to be sold, as indicated by the fact that with the exception of the one display placard, each piece either contained a price mark or a mailing permit with space for address. This, he contends, supports his theory that product and literature were not to be distributed together, hence cannot be said to accompany each other.

"We find two answers to this contention. In the first place, labeling and advertising are not mutually exclusive, and the same matter may serve both purposes. As the Court of Appeals for the Ninth Circuit states in *United States* v. *Research Laboratories*, 126 F. 2d 42, 'Most, if not all, labeling is advertising. The term "labeling" is defined in the Act as including all printed matter accompanying any article. Congress did not, and we cannot, exclude from the definition printed matter which constitutes advertising.' See also *United States* v. *Paddock*, 67 Fed. Supp. 819. In the second place, the placing of the mailing permit or the price tag on the literature cannot insulate appellant from liability for introducing the drugs and their related descriptive matter into interstate commerce together by consignment to the same consignee for distribution by him. The evidence is clear that the booklets were actually displayed on racks close to the counter where the products were sold and that they were necessary to inform the purchasing public of the uses to which these products were to be put.

"We agree with appellee that 'the correct concept of "accompaniment" is one of a commercial or business association.' As stated in the *Rakos* case *supra*, 'misbranding has true significance only in terms of the consumer. * * * "Accompany" as used in this Act is used to describe a relationship between an article of drug and its labeling. Since there "can be no question that among the usual characteristics of labeling is that of informing a purchaser of the uses of an article to which the labeling relates" (citing the decision of this court in *United States* v. *Lee*, *supra*) the booklets here involved should be scrutinized from this viewpoint. In the sense just stated, if the booklets are not labeling, then the products * * * have none.'

"We, too, are convinced that the test is not of physical contiguity but of textual relationship. Viewed thus, the products and literature here involved were interdependent because without the latter, the former lacked the labeling necessary to inform the purchasing public of their uses and purposes—it is significant that the labels printed on the immediate containers did not indicate the purposes for which the articles were to be used. Hence, the literature was intended and essential to explain the alleged uses of the products. They constituted a supplement to the label physically attached to the product container. One of the health food dealers in whose store the

Kordel products were sold admitted that if he were buying one of the products he would have to go to 'reliable sources' to know to what use to put the product. Presumably those reliable sources were the booklets displayed in racks close by the counter where the drugs were dispensed or lying on the counters where they were available to the public and could be picked up and examined. Some also were wrapped with merchandise or handed to customers.

"We agree with the District Court that, because the literature was shipped by appellant or at his order, to the same consignees as the products, related to those products, and was intended to be distributed in relation to them, it did accompany the products into interstate commerce within the definition of the Act. To hold otherwise would be to permit evasion of the Act by the very easy subterfuge of printing a purchase price or a mailing permit on advertising matter otherwise unquestionably accompanying products into interstate commerce.

"With respect to the misrepresentations contained in the accompanying literature we think there can be no serious question. The two booklets, 'Nutrition Guide,' and 'What you can do about relieving the agonies of Arthritis,' were written by appellant who, in the latter, is described as 'America's leading vitamin and diet expert.' 'Health Today, Spring 1945,' is edited by the same 'famous nutrition and vitamin authority.' While all purport to be scientific publications of general interest apart from the articles produced and marketed by appellant, written by an expert in the field, in fact, all are replete with references to the Kordel products and their uses to prevent, ameliorate or cure a vast and diverse variety of ailments, and each conveniently closes with a price list of the various Kordel products recommended for use therein. All are concerned primarily with promoting the sale of the various products by explaining the need for each, along with extravagant claims as to the usefulness of each. A study of the three pamphlets reveals that the products therein described are recommended for relieving stomach agonies, general weakness, anemia, premature old age, high blood pressure, liver troubles, failing eyesight, sore feet; maintaining blood energy, muscular activity, sound teeth and gums, healthy skin, hair and eyes, normal functioning of the pituitary and thyroid glands, stomach, intestines, colon, liver and kidneys; and preventing arthritis and stiff joints, excess weight, catarrh, nervous breakdown, sterility, and paralysis.

"Thus the scheme devised by appellant for the distribution of his products and related literature contemplates an elaborate system of self-diagnosis and medication. The danger inherent in this system lies not in any positive unwholesomeness of the articles themselves. As to them as such there is no charge and it may be that they are quite harmless in and of themselves. The danger however, lies in the fact that ignorant and gullible persons are likely to rely upon them instead of seeking professional advice for conditions they are represented to relieve or prevent. The Government introduced the evidence of many very eminent men in the medical profession to prove the dangerously misleading character of the literature in that the drugs were useless to combat the conditions they were represented to relieve, while delay in correct diagnosis and treatment for those conditions might render the treatment useless. As one of them stated, the literature encouraged people to experiment with themselves and that meant they were gambling with their health and life. He branded as scientifically ridiculous and nonsensical various of the claims and, when asked whether he would say that the products in themselves were

harmful, replied, 'They are definitely harmful in that they encourage a patient with a serious disease to experiment with himself when he should seek medical advice and precise diagnosis and therapy.'

"All were agreed that while the claims were absurd and fantastic, they were dangerous in that they tended to lull people into a false sense of security in reliance on the drugs when they might need professional diagnosis and treatment for conditions which might respond to treatment if correctly diagnosed early enough, but which might become much more serious if not taken care of early. Since the literature which we have already held accompanied the products embodies such misleading representations, it constitutes misbranding within the meaning of the Act.

"Appellant contends that, since the current proceedings are criminal, he is entitled to a strict construction of the Act, with proof of the violation, if any, beyond a reasonable doubt. Courts for a long time have been committed to the doctrine of giving statutes intended to protect the public health a very liberal construction. As stated in Sutherland on Statutory Construction (Vol. III, sec. 7202), 'The public and social purposes served by such legislation greatly exceed the inconvenience and hardship imposed upon the individual, and therefore the former is given greater emphasis in the problems of interpretation. Therefore the courts are inclined to give health statutes a liberal interpretation despite the fact that such statutes are primarily penal in nature and frequently impose criminal penalties.' To the same effect is the ruling in *United States* v. *Dotterweich*, 321 U. S. 277, where the Court said, 'The prosecution to which Dotterweich was subjected is based on a now familiar type of legislation whereby penalties serve as effective means of regulation. Such legislation dispenses with the conventional requirement for criminal conduct—awareness of some wrongdoing.'

"We think there can be no doubt of the sufficiency of the evidence to sustain the charge beyond a reasonable doubt.

"Appellant strongly relies upon *Alberty* v. *United States*, 159 F. 2d 278, to sustain his proposition that booklets and the like, not shipped at the time of the articles, do not 'accompany' the article when they are introduced or offered for introduction into interstate commerce, and consequently cannot 'then and there' misbrand them. The Circuit Court of Appeals for the Ninth Circuit there reversed an order overruling a demurrer to an information and remanded the cause with directions to dismiss the information. It distinguished three of the cases to which we have referred (*United States* v. *Research Laboratories*, *United States* v. 7 *Jugs* * * * *Rakos*, and *United States* v. *Lee*) on the ground that all involved civil proceedings and construed the Act liberally. We have already indicated that under the authorities cited, we do not consider the distinction applicable to the construction of the statute here involved. To the extent that the court limits the definition of the word 'accompany' to mean only physical association and contiguity, we do not agree with its reasoning and are convinced that it is not in harmony with those authorities.

"We find no merit in appellant's contention that he should have been prosecuted by indictment rather than by information. Section 303 (a) upon which the informations were based (21 U. S. C. A. sec. 333 (a)) provides that any person violating any of the provisions of section 201 shall be guilty of a misdemeanor, and subject to imprisonment for not more than one year or a fine of $1,000 or both, unless he has already been convicted of a prior offense under the same section. The charges were brought under this section. That being

the case, there was no necessity for prosecution by indictment. See *United States* v. *Wells Co.*, 186 Fed. 248 (holding violation of the 1906 Food and Drugs Act not an infamous crime). See also *Falconi* v. *United States* 280 Fed. 766, and cases there cited. *Judgments affirmed.*"

The above opinion was followed by the filing of a petition for rehearing, which was denied on January 22, 1948. A petition for a writ of certiorari was thereupon filed in the United States Supreme Court and was subsequently granted. On November 22, 1948, the following decision was handed down by that court:

MR. JUSTICE DOUGLAS: "This case and *United States* v. *Urbuteit*, decided this day, are here on certiorari to resolve a conflict among the circuits in the construction of the Federal Food, Drug, and Cosmetic Act of June 25, 1938. 52 Stat. 1040, 21 U. S. C. § 301 *et seq.*

"Kordel is charged by informations containing twenty counts of introducing or delivering for introduction into interstate commerce misbranded drugs. He was tried without a jury, found guilty, and fined two hundred dollars on each count. This judgment was affirmed on appeal. 164 F. 2d 913. Kordel writes and lectures on health foods from information derived from studies in public and private libraries. Since 1941 he has been marketing his own health food products; which appear to be compounds of various vitamins, minerals and herbs. The alleged misbranding consists of statements in circulars or pamphlets distributed to consumers by the vendors of the products, relating to their efficacy. The petitioner supplies these pamphlets as well as the products to the vendors. Some of the literature was displayed in stores in which the petitioner's products were on sale. Some of it was given away with the sale of products; some sold independently of the drugs; and some mailed to customers by the vendors.

"It is undisputed that petitioner shipped or caused to be shipped in interstate commerce both the drugs and the literature. Seven of the counts charged that the drugs and literature were shipped in the same cartons. The literature involved in the other counts was shipped separately from the drugs and at different times—both before and after the shipments of the drugs with which they were associated. The question whether the separate shipment of the literature saved the drugs from being misbranded within the meaning of the Act presents the main issue in the case.

"Section 301 (a) of the Act prohibits the introduction into interstate commerce of any drug that is adulterated or misbranded.[1] It is misbranded according to § 502 (a) if its 'labeling is false or misleading in any particular,' unless the labeling bears 'adequate directions for use.' § 502 (f). The term

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[1] Section 301 in relevant part reads as follows:

"The following acts and the causing thereof are hereby prohibited:

(a) The introduction or delivery for introduction into interstate commerce of any food, drug, device, or cosmetic that is adulterated or misbranded.

(b) The adulteration or misbranding of any food, drug, device, or cosmetic in interstate commerce.

(c) The receipt in interstate commerce of any food, drug, device, or cosmetic that is adulterated or misbranded, and the delivery or proffered delivery thereof for pay or otherwise.

* * * * * * *

(k) The alteration, mutilation, destruction, obliteration, or removal of the whole or any part of the labeling of, or the doing of any other act with respect to, a food, drug, device, or cosmetic, if such act is done while such article is held for sale after shipment in interstate commerce and results in such article being misbranded."

labeling is defined in § 201 (m) to mean 'all labels[2] and other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article.' Section 303 makes the violation of any of the provisions of § 301 a crime.[3]

"In this case the drugs and the literature had a common origin and a common destination. The literature was used in the sale of the drugs. It explained their uses. Nowhere else was the purchaser advised how to use them. It constituted an essential supplement to the label attached to the package. Thus the products and the literature were interdependent, as the Court of Appeals observed.

"It would take an extremely narrow reading of the Act to hold that these drugs were not misbranded. A criminal law is not to be read expansively to include what is not plainly embraced within the language of the statute (*United States* v. *Resnick*, 299 U. S. 207; *Kraus & Kraus* v. *United States*, 327 U. S. 614, 621–622), since the purpose fairly to apprise men of the boundaries of the prohibited action would then be defeated. *United States* v. *Sullivan*, 332 U. S. 689, 693; *Winters* v. *New York*, 333 U. S. 507. But there is no canon against using common sense in reading a criminal law, so that strained and technical constructions do not defeat its purpose by creating exceptions from or loopholes in it. See *Roschen* v. *Ward*, 279 U. S. 337, 339.

"It would, indeed, create an obviously wide loophole to hold that these drugs would be misbranded if the literature had been shipped in the same container but not misbranded if the literature left in the next or in the preceding mail. The high purpose of the Act to protect consumers who under present conditions are largely unable to protect themselves in this field[4] would then be easily defeated. The administrative agency charged with its enforcement[5] has not given the Act any such restricted construction.[6] The textual structure of the Act is not agreeable to it. Accordingly, we conclude that the phrase 'accompanying such article' is not restricted to labels that are on or in the article or package that is transported.

"The first clause of § 201 (m)—all labels 'upon any article or any of its containers or wrappers'—clearly embraces advertising or descriptive matter that goes with the package in which the articles are transported. The second clause—'accompanying such article' has no specific reference to packages, containers or their contents as did a predecessor statute. See *Seven Cases* v.

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[2] The term label is defined as "a display of written, printed, or graphic matter upon the immediate container of any article." § 201 (k).

[3] "SEC. 303. (a) Any person who violates any of the provisions of section 301 shall be guilty of a misdemeanor and shall on conviction thereof be subject to imprisonment for not more than one year, or a fine of not more than $1,000, or both such imprisonment and fine; but if the violation is committed after a conviction of such person under this section has become final such person shall be subject to imprisonment for not more than three years, or a fine of not more than $10,000, or both such imprisonment and fine.

"(b) Notwithstanding the provisions of subsection (a) of this section, in case of a violation of any of the provisions of section 301, with intent to defraud or mislead, the penalty shall be imprisonment for not more than three years, or a fine of not more than $10,000, or both such imprisonment and fine."

The informations, in charging violations of § 301 (a), did not allege that the acts committed were done "with intent to defraud." Hence the maximum penalty was that provided in § 303 (a), *viz*, imprisonment for not more than a year, or a fine of not more than $1,000, or both. Prosecution by information was therefore authorized by the statute (see *Duke* v. *United States*, 301 U. S. 492) and by § 7 (a) of the Rules of Criminal Procedure.

[4] See *United States* v. *Dotterweich*, 320 U. S. 277, 280; *United States* v. *Sullivan*, *supra*, p. 696.

[5] See § 701 and § 201 (c), 1940 Reorg. Plan No. IV, § 12, 54 Stat. 231, 5 U. S. C. § 133 (u).

[6] The Federal Security Agency by regulation (21 C. F. R. Cum. Supp. § 2.2) has ruled:

"Labeling includes all written, printed, or graphic matter accompanying an article at any time while such article is in interstate commerce or held for sale after shipment or delivery in interstate commerce."

United States, 239 U. S. 510, 513, 515. It plainly includes what is contained within the package whether or not it is 'upon' the article or its wrapper or container. But the second clause does not say 'accompanying such article in the package or container,' and we see no reason for reading the additional words into the text.

"One article or thing is accompanied by another when it supplements or explains it, in the manner that a committee report of the Congress accompanies a bill. No physical attachment one to the other is necessary. It is the textual relationship that is significant. The analogy to the present case is obvious. We need not labor the point.

"The false and misleading literature in the present case was designed for use in the distribution and sale of the drug, and it was so used. The fact that it went in a different mail was wholly irrelevant whether we judge the transaction by purpose or result. And to say that the prior or subsequent shipment of the literature disproves that it 'is' misbranded when introduced into commerce within the meaning of § 301 (a), is to overlook the integrated nature of the transactions established in this case.

"Moreover, the fact that some of the booklets carried a selling price is immaterial on the facts shown here. As stated by the Court of Appeals, the booklets and drugs were nonetheless interdependent; they were parts of an integrated distribution program. The Act cannot be circumvented by the easy device of a 'sale' of the advertising matter where the advertising performs the function of labeling.

"Petitioner points out that in the evolution of the Act the ban on false advertising was eliminated, the control over it being transferred to the Federal Trade Commission. 52 Stat. 114, 15 U. S. C. § 55 (a). We have searched the legislative history in vain, however, to find any indication that Congress had the purpose to eliminate from the Act advertising which performs the function of labeling. Every labeling is in a sense an advertisement. The advertising which we have here performs the same function as it would if it were on the article or on the containers or wrappers. As we have said, physical attachment or contiguity is unnecessary under § 201 (m) (2).

"There is a suggestion that the offense in this case falls under § 301 (k) of the Act which includes misbranding of a drug while it is held for sale after shipment in interstate commerce.[7] Since the informations contain no such charge, it is therefore claimed that the judgment must be reversed. We do not agree. Section 301 (k) has a broad sweep, not restricted to those who introduce or deliver for introduction drugs in interstate commerce.[8] See *United States* v. *Sullivan*, *supra*. Nor is it confined to adulteration or misbranding as is § 301 (a). *Id.* It is, however, restricted to cases where the article is held for sale after shipment in interstate commerce; and, unlike § 301 (a) it does not reach situations where the manufacturer sells directly to the consumer. Cf. *United States* v. *Urbuteit*, *supra*. Hence we conclude that we do not disturb the statutory scheme when we refuse to take from § 301 (a) what is fairly included in it in order to leave the matter wholly to the service of § 301 (k). The reach of § 301 (a) is in this respect longer. Such a transfer to § 301 (k) would create a new hiatus in the Act and thus disturb the pattern which we discern in it.

[7] See note 1, *supra*.

[8] The purpose of § 301 (k) was described in H. Rep. No. 2139, 75th Cong., 3d Sess. 3 (1938), as follows:

"In order to extend the protection of consumers contemplated by the law to the full extent constitutionally possible, paragraph (k) has been inserted prohibiting the changing of labels so as to misbrand articles held for sale after interstate shipment."

"We have considered the other objections tendered by petitioner and find them without merit. *Affirmed.*"

MR. JUSTICE BLACK, *with whom* MR. JUSTICE FRANKFURTER, MR. JUSTICE MURPHY, *and* MR. JUSTICE JACKSON *concur, dissenting:* "I agree with the court's interpretation of § 502 (a) and § 201 (m) of the Pure Food and Drug Act. These sections considered together provide a definition for the 'misbranding' of drugs. I agree that a drug is misbranded within the meaning of the statute if false and misleading written, printed, or graphic matter is either placed upon the drug, its container or wrappers, or used in the sale of the drug as a supplement to the package label to advise consumers how to use the drug. I agree that false labels may, within the meaning of the statute, 'accompany,' that is go along with, a drug on its interstate journey even though not in the same carton, on the same train, in the same mail, or delivered for shipment the same day. But these agreements do not settle all the problems in this case.

"The Pure Food and Drug Act does not purport to make all misbranding of drugs within the foregoing definition a federal offense. Congressional power to pass the Act is based upon the commerce clause. Consequently misbranding is only an offense if the misbranded drugs bear the statutorily defined relationships to interstate commerce. For illustration, if a person misbranded a drug which had not been and was not thereafter introduced into interstate commerce, there would be no violation of the federal Act, whatever violation there might be of state law.

"As we pointed out in *United States* v. *Sullivan*, 332 U. S. 689, the Pure Food and Drug Act creates several offenses each of which separately depends upon the relationship the misbranded drug then bears to interstate commerce. Section 301 (a) forbids the 'introduction or delivery for introduction into interstate commerce' of misbranded drugs; § 301 (b) forbids misbranding while the drugs are 'in interstate commerce'; § 301 (c) prohibits the 'receipt' of such drugs in interstate commerce; and § 301 (k) forbids misbranding while drugs are 'held for sale after shipment in interstate commerce.'

"The twenty counts of the information upon which this petitioner's conviction rests, charge that he had introduced drugs into interstate commerce, and that 'when' he so introduced the drugs, they were 'misbranded . . . in that . . . statements appearing in . . . bulletins and booklets *accompanying*' the drugs 'were false and misleading.' [Emphasis supplied.] The undisputed evidence as to thirteen of these counts showed that when the drugs were 'introduced' into interstate commerce for shipment, they were not within any fair meaning of the word 'accompanied' by the printed matter relied on as 'labeling.' The evidence under one count was that the drugs were shipped July 10, 1942, while the booklets said to be 'labels' were sent a year and a half later, January 18, 1944. Thus, each of these counts charged a violation of the separate and distinct offense of introducing misbranded drugs into interstate commerce, prohibited by § 301 (a). The evidence proves the offense, if any, of violation of § 301 (k), which prohibits the misbranding of drugs while held for sale after an interstate shipment.

"The court's interpretation of § 301 (a) seems to me to create a new offense to make it a crime to introduce drugs into interstate commerce if they should subsequently be misbranded, even so long as eighteen months later while held for sale. This judicial action is justified in part on the ground that the offense Congress created in § 301 (k) for holding misbranded drugs for sale after interstate shipment might not reach all situations covered by the congressionally created offense defined by § 301 (a). If as the Court believes, Congress in

§ 301 (k) has limited the situations for which it will direct punishment for holding misbranded articles for sale, I cannot agree that we should rewrite § 301 (a) so as to broaden its coverage. If Congress left a hiatus, Congress should fill it if it so desires. While I do not doubt the wisdom of separating these offenses as Congress has here done, we must remember that there are dangers in splitting up one and the same transaction into many offenses. See *Blockberger* v. *United States*, 284 U. S. 299, 304–305.

"These are serious offenses. While petitioner was fined only $200 on each count, or a total of $4,000, the maximum allowable punishment was $1,000 per count and imprisonment for one year, or for three years under other circumstances. § 303 (a). The approach of Congress in this field of penal regulation has been cautious. The language used by Congress in the present law in defining new offenses has been marked by precision. I think we should exercise a similar caution before reading into the 'introduction to interstate commerce' offense, conduct which patently fits into the 'held for sale' offense.

"I would reverse the judgment here insofar as it rests on the thirteen counts in which the Government charged offenses under § 301 (a) and failed to prove them."

2581. Misbranding of Gotu Kola tablets, fenugreek tea, Bolax tablets, Garlic Plus tablets, Ribotabs tablets, Minerals Plus tablets, sarsaparilla tea, Everm wheat germ oil capsules, Kordel tablets, Ormotabs tablets, Cetabs tablets, Fero-B-Plex tablets, Kordel-A capsules, Niamin tablets, Papaya Plus tablets, and Matto tablets. U. S. v. 134 Packages, etc. (and 3 other seizure actions). (F. D. C. Nos. 11810, 15807, 15916, 15926. Sample Nos. 49028–F, 28330–H, 28332–H, 28335–H, 28336–H, 28338–H, 28340–H, 28363–H to 28371–H, incl., 28373–H to 28376–H, incl., 28390–H, 28392–H, 28394–H to 28396–H, incl., 28398–H, 29402–H to 29412–H, incl.)

LIBELS FILED: February 22, 1944, and April 16 and May 3 and 4, 1945, Northern District of California, Southern District of Ohio, and Western District of Washington.

ALLEGED SHIPMENT: Between the approximate dates of December 6, 1943, and March 21, 1945, by Lelord Kordel Products and Nutrition Enterprises, from Chicago, Ill.

PRODUCT: 134 packages of *Gotu Kola tablets*, 1,794 packages of *fenugreek tea*, 153 cartons of *Bolax tablets*, 104 cartons of *Garlic Plus tablets*, 239 cartons of *Papaya Plus tablets*, 184 cartons of *Ribotabs tablets*, 404 cartons of *Minerals Plus tablets*, 76 boxes of *sarsaparilla tea*, 209 cartons of *Everm wheat germ oil capsules*, 19 cartons of *Kordel tablets*, 242 cartons of *Ormotabs tablets*, 80 cartons of *Matto tablets*, 61 packages of *Cetabs tablets*, 411 packages of *Fero-B-Plex tablets*, 64 packages of *Kordel-A capsules*, and 41 packages of *Niamin tablets* at San Francisco, Calif., Cincinnati, Ohio, and Seattle, Wash.

Analyses disclosed that the *Papaya Plus tablets* consisted essentially of plant material containing oil of wintergreen and vitamin B_1, and that the *Matto tablets* consisted of powdered plant material. The results of analyses of the other products were essentially the same as the results of analyses reported in the preceding notice of judgment, No. 2580, with respect to the products of the same names involved therein.

NATURE OF CHARGE: *Gotu Kola tablets, fenugreek tea, Bolax tablets, Garlic Plus tablets, Ribotabs tablets, Minerals Plus tablets, sarsaparilla tea, Everm wheat germ oil capsules, Kordel tablets, Ormotabs tablets, Cetabs tablets, Fero-B-Plex tablets, Kordel-A capsules,* and *Niamin tablets.* Misbranding,

Section 502 (a), the labeling of these articles bore false and misleading statements which were similar to the false and misleading statements in the labeling of the products involved in the preceding notice of judgment, No. 2580. Further misbranding, Section 502 (a), the statements "A difference in medical opinion exists concerning the value of garlic tablets in easing distress of high blood pressure. In favor of such value are the opinions of experts qualified by scientific trading to evaluate" displayed on the label of the *Garlic Plus tablets* were misleading since there is no difference of opinion among qualified experts as to the lack of value of garlic tablets for the relief of the distress of high blood pressure.

Papaya Plus tablets. Misbranding, Section 502 (a), certain statements in the labeling of the article were false and misleading. These statements represented and suggested that the article would be effective in assisting the digestion and assimilation of other foods; that it would be efficacious in the cure of scurvy and dysentery; that consumption of the article would make one strong and healthy; that the article would accomplish near-miraculous cures; that it possessed extraordinary nutritive values; that it would have a normalizing effect; that it would promote the generation and flow of salivary and gastric juices; that it would reduce superacidity of the stomach and relieve the symptoms of acidosis; that it would be efficacious in the treatment of excessive generation of gas on the stomach; that it was a valuable aid in digestion, particularly where normal digestion is impaired or disturbed; that it was a remedy for many ailments; and that it would be efficacious as a heart stimulant. The article would not be effective to fulfill the promises of benefit stated and implied.

Matto tablets. Misbranding, Section 502 (a), certain statements in the labeling of the article were false and misleading. These statements represented and suggested that the article would relieve that exhausted feeling; that it would enable one to endure long marches over periods of months with but very little and irregular food; that it was an exhilarating stimulant and diuretic; that it would enable one to pass days without solid food and suffer no great hunger; that it was a first-class stimulant and a general scorbutic tonic; that it would facilitate digestion and assist the functioning of the kidneys; and that it would be efficacious for nervous and excited persons. The article would not be effective to fulfill the promises of benefit expressed and implied. Further misbranding, Section 502 (a), the statements "As a dietary supplement * * * The need in human nutrition for Matto has not been officially established" displayed on the label of the *Matto tablets* were misleading since the article was not a nutritional factor and had no value as a dietary supplement.

The *Gotu Kola tablets*, *Ribotabs tablets*, *Minerals Plus tablets*, *Everm wheat germ oil capsules*, *Cetabs tablets*, *Fero-B-Plex tablets*, *Kordel-A capsules* and *Niamin tablets* were alleged also to be misbranded under the provisions of the law applicable to foods, as reported in notices of judgment on foods.

DISPOSITION: April 6, 1944, and August 11 and September 7, 1945. Default decrees of condemnation and destruction.

2582. Action for criminal contempt for violation of terms of injunction. U. S. v. Edgar H. Gremore. Plea of not guilty. Tried to the court; verdict of guilty. Sentence of 6 months in prison suspended and defendant placed on probation for 3 years. (Inj. No. 82.)

INFORMATION FILED: On or about December 21, 1948, Eastern District of Wisconsin, against Edgar H. Gremore, Florence, Wis.

NATURE OF CHARGE: That the defendant in willful disobedience of the decree of injunction against the introduction into interstate commerce of products misbranded under Section 502 (a) [*See* notice of judgment on drugs and devices No. 2306], shipped in interstate commerce to Stephenson, Mich., Oak Park, Ill., and Chicago, Ill., on or about November 29, 1945, and October 19 and 26, 1948, quantities of a product designated *Nature's Vegetation*, which was misbranded under Section 502 (a); and that by reason of such shipments, the defendant was in criminal contempt of the permanent injunction issued on June 11, 1945.

DISPOSITION: A plea of not guilty having been entered, the case came on for trial before the court on January 24, 1949. At the conclusion of the trial, the court found the defendant guilty of contempt and sentenced him to serve 6 months in prison. The sentence was suspended and the defendant was placed upon probation for 3 years on the condition that he abandon the sale and marketing of the product by any means whatsoever, whether interstate or intrastate.

2583. Misbranding of Frenco's Papain, Frenco's Pap-Tabs, New Minute Py-O-Ten, and Frenco's Papaya Tooth Powder. U. S. v. Chester D. French (Frenco Laboratories). Plea of nolo contendere. Fine of $105 and sentence of 6 months in jail; jail sentence suspended for 6 months and defendant placed on probation. (F. D. C. No. 17786. Sample Nos. 74297–F to 74299–F, incl., 29949–H to 29951–H, incl.)

INFORMATION FILED: On or about April 29, 1946, District of Arizona, against Chester D. French, trading as Frenco Laboratories, at Nogales, Ariz.

ALLEGED SHIPMENT: On or about October 17, 1944, and March 23, May 19, and August 13, 1945, from the State of Arizona into the State of California.

PRODUCT: Analyses showed that *Frenco's Papain and New Minute Py-O-Ten* consisted essentially of plant material containing a milk-clotting enzyme, probably papain; that a portion of *Frenco's Pap-Tabs* consisted essentially of compounds of calcium, magnesium, bismuth, and carbonate, together with some acid-insoluble matter and a milk-clotting enzyme, probably papain; that the remainder of *Frenco's Pap-Tabs* consisted essentially of bismuth, calcium, and magnesium carbonates or oxides, papain, starch, and a trace of cerium; and that *Frenco's Papaya Tooth Powder* consisted essentially of sodium, calcium, and magnesium carbonates and chlorides, papain, starch, and soap.

LABEL, IN PART: "Frenco's Papain Powdered Absolute," "Frenco's Pap-Tabs," "New Minute Py-O-Ten," and "Frenco's Papaya Tooth Powder."

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements on the labels of the articles and in circulars entitled "Frenco's Papain Powdered Absolute," "Frenco Laboratories of Nogales," and "Frenco Pap-Tabs" were false and misleading since the articles would not be effective for the purposes and would not fulfill the promises of benefits suggested and implied by the statements. The false and misleading statements represented:

That *Frenco's Papain* when used as a vaginal douche solution material, it

would be effective in the diseases of women to correct leukorrhea, unhealthy mucus, and pus excretions; that it would be effective in the treatment of mild indigestion and acute indigestion; that it was one of the greatest antacids; that when employed in a cosmetic cream, it would remove blemishes and would digest blemishes on the skin and the accumulation of the secretion in the pores; that its use in cooking would insure a more balanced and digestible diet; that it would reduce acidity in the system; that it would aid in the treatment locally of pyorrhea; that when dusted in cavities left by tonsillectomy operations, it would be of use in the treatment of such cavities; that it would be a very effective cough remedy; that it would be an adequate treatment for infections of the ears and sinuses; that it would give appreciable relief in chronic conditions developed following a cold; that when taken as directed, it would supply a substantial amount of protein and consequential amounts of vitamins B, D, and G; that it was an excellent specific for gastric distress and dyspeptic ailments; that when added to milk for those who have digestive difficulties, it would give excellent results; and that when employed in face cream, it would remove blemishes.

That *Frenco's Pap-Tabs* was "Nature's Great Digestant"; that it was a digestive tablet and a healing compound; that it would render the toxic poisons of the colon harmless; that it would be adequate for the treatment of digestive disorders from all angles; that it would be a great aid in the treatment of disturbed or subnormal digestion; that it would be highly effective for the relief of sour stomach, gas, indigestion, hyperacidity, nausea during menses and pregnancy, and pain around the heart caused by gas pressure; that it would be excellent for the relief of nausea caused by over-indulgence in alcoholic beverages and for the relief of nausea in attacks of sea, air, car, and train sickness; that it would be effective in the treatment of feeble and disordered digestion and of diseased conditions where the natural digestive process is deficient; that the daily use of the article would keep the digestive tract clean and healthy; that it would soothe and quiet the stomach and in most cases give decided relief in 10 to 15 minutes; that it would be helpful not only in extreme cases of distress but in all cases of distress; and that it would be effective in the treatment of gastric eructations and flatulence due to hyperacidity.

That *New Minute Py-O-Ten* would prevent insomnia and render food quickly digestible, and that it would be beneficial during periods of gastric distress.

That *Frenco's Papaya Tooth Powder* would be effective in digesting anything digestible, whether in acid, alkaline, or neutral solution, which may cling to the teeth, between the teeth, in cavities, or under the gums; that it would digest unhealthy pus secretions coming from diseased condition of gums or process; that it would be effective in the treatment of pyorrhea and sore gums; and that it would have a healing effect upon the gums.

Further misbranding, Section 502 (a), the label statement "Contains * * * Calcium, Magnesium, Kaolin, Bismuth" with respect to a portion of the *Frenco's Pap-Tabs*, was false and misleading since the article contained no kaolin and did not contain calcium, magnesium, and bismuth as such, but instead contained compounds of such minerals.

DISPOSITION: January 7, 1949. A plea of nolo contendere having been entered, the court imposed a fine of $105 and sentenced the defendant to serve 6 months in prison. The prison sentence was suspended for 6 months, and the defendant was placed on probation.

2584. Misbranding of vitamin products. U. S. v. Vitamin Stores, Inc. Plea of nolo contendere. Fine of $250 and costs. (F. D. C. No. 24222. Sample Nos. 20534–H to 20536–H, incl., 40284–H, 40840–H, 67304–H.)

INFORMATION FILED: March 15, 1948, District of Nebraska, against Vitamin Stores, Inc., Omaha, Nebr.

ALLEGED SHIPMENT: On or about July 16 and November 1 and 14, 1946, and March 28, 1947, from the State of Nebraska into the State of Missouri.

LABEL, IN PART: "High Potency Vita-Chrome Improved Tablets * * * Vita-Chrome Co. Omaha, Neb. Each tablet contains: Calcium Pantothenate 30 mgm. * * *, Vitamin B_1 1.5 mgm. (150%), Vitamin B_2 2 mgm. (100%), Vitamin B_6 250 micrograms * * *, Niacin 5 mgm. (requirement not established), Paraminobenzoic Acid 10 mgm. * * *, Cystine 5 mgm."; "Superee High Potency Vitamin E Each Capsule Contains: Concentrate of Natural, mixed Tocopherols distilled from vegetable oils—equivalent in biological activity to 30 milligrams of Alpha Tocopherol. [or "Pure Wheat Germ Oil Derived From Freshly Milled Wheat Germ"] * * * Distributed by Vitamin Industries 1320 Farnam St. Omaha 2, Nebr."; "Dia-B-Plex Tablets Super Potency B Complex The Vitamin Store Omaha, Nebr. Each tablet contains: Vitamin B_1, 6 milligrams (600%), Vitamin B_2, 3 milligrams (150%), Vitamin B_6, .25 milligrams * * *, Calcium Pantothenate, 1 milligram * * *, Niacin, 20 milligrams"; "De-A-Tol Vitamin D Each Capsule Contains: 50,000 U.S.P. Units * * * Distributed by The Vitamin Store Omaha, Nebr."; and "Improved Dietrim Capsules * * * Distributed By The Dietrim Co. 1320 Farnam St. Omaha 2, Nebraska Ingredients: Each six capsules contain: Vitamin B_1 6 mgm. (600%), Vitamin B_2 2 mgm. (100%), Vitamin B_6 300 mgm. * * * Vitamin C 75 mgm. (250%), Niacinamide 10 mgm. * * *, Calcium Pantothenate 750 mgm. * * * Plus Essential Amino Acids from Casein Hydrolysates."

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements in accompanying circulars entitled "Triple XXX Vita-Chrome B Complex," "Winter Vitamins," and "Price List Vitamins and Vitamin Preparations," a booklet entitled "Dietrim Plan To Help You Reduce Your Figure," and a leaflet entitled "Do You Want to Reduce Your Figure" were false and misleading. The statements represented and suggested that the *Vita-Chrome tablets* would be efficacious to furnish buoyant health and energy, and that it would restore color to gray hair; that the *vitamin E capsules* and *wheat germ oil* in combination would be efficacious in the treatment of heart disease, arteriosclerosis, hypertension, rheumatic heart disease, and old and new coronary heart disease; that it would help the failing heart, eliminate anginal pain, and prevent the destruction of platelets; and that it would increase the blood supply to the individual muscles of the heart, thus aiding muscle repair; that the *Dia-B-Plex tablets* would be efficacious in the treatment of diabetes and would enable the diabetic user to reduce the use of insulin or eliminate the use of insulin; that the *De-A-Tol capsules* would be an adequate treatment for arthritis; and that the *Dietrim capsules* would be efficacious to reduce the figure; that it was a protein diet supplement which would help to reduce food intake by supplying the material for new muscle tissue without supplying material which deposits fat; that it would guard the user's health; that it contained essential important vitamins that may be lacking when the food intake is cut down and concentrated proteins in the form of amino acids to provide material for the replacement of worn-out muscles and other tissues not containing fats; that it would protect

the user from the vitamin deficiencies which lead to excessive tiredness, nervousness, crossness, and irritability; that it would nourish the body while reducing; and that it would help to control the appetite. The articles would not be efficacious for such purposes and would not fulfill the promises of benefits stated and implied.

DISPOSITION: November 4, 1948. A plea of nolo contendere having been entered, the court imposed a fine of $250 and costs.

2585. Misbranding of Paracelsus. U. S. v. 24 Cans * * *. (F. D. C. No. 24898. Sample No. 34235-K.)

LIBEL FILED: June 29, 1948, Northern District of California.

ALLEGED SHIPMENT: By the American Biochemical Corp., from Cleveland, Ohio. The product was shipped on or about May 3, 1948, and a number of reprints from the "Lets Live Newsmagazine" were shipped during February 1948.

PRODUCT: 24 cans of *Paracelsus*, each containing 1-pound, 5-ounces, at Oakland, Calif., together with a number of reprints from the "Lets Live Newsmagazine" entitled "Malnutrition, Disease, Due to Mineral Lack." Examination showed that the product was a mineral mixture containing per ¾ teaspoon, 66 milligrams of calcium and 0.55 milligram of iron, or 8.8 percent of the adult minimum daily requirements for calcium and iron.

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements in the reprint were false and misleading. These statements represented and suggested that the article was effective to prevent and cure malnutrition and disease, to provide pep, to stimulate hormone production, and to prevent and cure arthritis; and that all individuals suffered from mineral deficiency and would benefit by use of the article. The article was not effective for such purposes, and it was not capable of fulfilling the promises of benefit stated and implied.

Further misbranding, Section 502 (a), the following label statements were false and misleading since if taken as directed the article would supply materially less calcium and iron than stated: "When Taken According to Direction Will Supply Percentage of Daily Requirements as Listed:

	Calcium				*Iron*
Man	13.50%	*	*	*	16.00%
Woman	13.50%	*	*	*	16.00%
Pregnancy latter half	7.00%	*	*	*	12.75%
Lactation	5.25%	*	*	*	12.75%
Children 1 to 9 years	10.75%	*	*	*	19.20%
Children 10 to 12 years	9.00%	*	*	*	16.00%
Girls 13 to 15 Years	8.00%	*	*	*	13.00%
Boys 13 to 15 years	7.50%	*	*	*	13.00%
Girls 16 to 20 years	10.50%	*	*	*	13.00%
Boys 16 to 20 years	7.50%	*	*	*	13.00%

The article was alleged also to be adulterated and misbranded under the provisions of the law applicable to foods, as reported in notices of judgment on foods.

DISPOSITION: September 21, 1948. Default decree of condemnation and destruction:

2586. Misbranding of National R Solution. U. S. v. 22 Bottles * * *. (F. D. C. No. 25116. Sample No. 2721-K.)

LIBEL FILED: July 22, 1948, District of Columbia.

ALLEGED SHIPMENT: On or about April 12, 1948, by the National Drug Co., from Philadelphia, Pa.

PRODUCT: 22 4-ounce bottles of *National R Solution* at Washington, D. C.

NATURE OF CHARGE: Misbranding, Section 502 (a), the label statements "Indications: For use as a mild astringent application in inflammation of mucous membranes of the urethra" and "Indications: For use as a mild astringent application in inflammation of mucous membranes" were false and misleading since the article would not be effective for the treatment of the conditions stated and implied.

DISPOSITION: December 28, 1948. Default decree of condemnation and destruction.

2587. Misbranding of P. P. P. U. S. v. 5 Cases * * *. (F. D. C. No. 25096. Sample No. 850–K.)

LIBEL FILED: On or about July 28, 1948, Southern District of Florida.

ALLEGED SHIPMENT: On or about March 26, 1948, by Rodeco Products, from Augusta, Ga.

PRODUCT: 5 cases, each containing 24 bottles, of P. P. P. at Tampa, Fla. Examination showed that the product consisted essentially of water, alcohol, potassium iodide, and extracts of plant drugs.

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements in the labeling of the article were false and misleading since they represented and suggested that the article was effective in the treatment of rheumatic conditions, pimples, boils, old sores, and many blood conditions, whereas it was not effective in the treatment of such conditions.

DISPOSITION: August 19, 1948. Default decree of condemnation and destruction.

2588. Misbranding of Dolcin tablets. U. S. v. 109 Bottles * * *. (F. D. C. No. 21961. Sample No. 64547–H.)

LIBEL FILED: December 10, 1946, District of New Jersey; amended libel filed September 11, 1947.

ALLEGED SHIPMENT: On or about November 8, 1946, by the Dolcin Corp., from New York, N. Y.

PRODUCT: 109 100-tablet bottles of *Dolcin tablets* at Newark, N. J. Examination indicated that the tablets consisted essentially of 2.6 grains of aspirin and 3.4 grains of calcium succinate.

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements on the labels of the article and in a circular enclosed with the article were false and misleading. The statements represented and suggested that the article was effective and adequate for the relief, treatment, and cure of all types of arthritis and rheumatism. The article was not effective and adequate for such purposes.

DISPOSITION: The Dolcin Corp. appeared as claimant and filed an answer denying that the product was misbranded as alleged in the libel. Thereafter, the claimant requested permission of the court to withdraw its claims and answer since it had changed the labeling of the product to omit the representations complained of in the libel and was therefore of the belief that no useful purpose would be served by contesting the case. On December 6, 1948, the court granted the claimant's request and entered a decree of condemnation and destruction.

2589. Misbranding of Atropine sulfate tablets. U. S. v. 4,996 Tubes * * *. (F. D. C. No. 25429. Sample No. 30279–K.)

LIBEL FILED: August 31, 1948, Southern District of California.

ALLEGED SHIPMENT: On or about February 13, 1948, by the Retort Pharmaceutical Co., from Long Island City, N. Y.

PRODUCT: 4,996 tubes of *atropine sulfate tablets* at Wilmington, Calif. Examination showed that the tubes contained materially fewer than 20 whole tablets, together with broken, chipped, and powdered tablets.

LABEL, IN PART: (Tubes) "20 Hypodermic Tablets 1/150 grain each Atropine Sulphate U. S. P."

NATURE OF CHARGE: Misbranding, Section 502 (a), the label statement "20 Tablets" was false and misleading since the tubes contained materially fewer whole tablets than declared.

DISPOSITION: October 19, 1948. Default decree of condemnation and destruction.

2590. Misbranding of Cravex. U. S. v. 30 Cartons, etc. (F. D. C. No. 25181. Sample No. 18254–K.)

LIBEL FILED: July 23, 1948, Northern District of Ohio.

ALLEGED SHIPMENT: On or about November 24, 1947, and March 18 and May 5, 1948, by Plant Products Co., Inc., from Burbank, Calif.

PRODUCT: 30 small and 12 large cartons of *Cravex* at Akron Ohio. Examination showed that the product consisted essentially of calcium and magnesium phosphates and glycerophosphates, caffeine, and milk sugar.

NATURE OF CHARGE: Misbranding, Section 502 (a), the following statements (on carton) "Cravex" and (on circular within carton) "It has been shown that alcohol chiefly affects the nervous system, which causes nervous irritability and frequently results in malnutrition. Cravex is a nerve tonic which contains several substances which are helpful in the treatment of both the causes and effects of over-indulgence" were false and misleading since the article was not a treatment for the causes and effects of overindulgence in liquor.

DISPOSITION: September 14, 1948. Default decree of condemnation and destruction.

2591. Misbranding of throat lozenges. U. S. v. 34 Cartons * * *. (F. D. C. No. 25505. Sample No. 3596–K.)

LIBEL FILED: August 27, 1948, District of Maryland.

ALLEGED SHIPMENT: On or about July 17, 1948, by W. M. Mearig, from New Holland, Pa.

PRODUCT: 34 cartons, each containing 12 boxes, of *throat lozenges* at Baltimore, Md. Examination showed that the product consisted essentially of licorice, capsicum, anise, sugar, and ⅛ minim of chloroform in each lozenge.

LABEL, IN PART: (Box) "Mearig Throat Lozenges * * * Each Lozenge contains not more than ½ minim of Chloroform."

NATURE OF CHARGE: Misbranding, Section 502 (a), the label statement "very helpful in the relief of most throat troubles" was false and misleading since the article would not be effective in the relief of throat troubles; and, Section 502 (e) (2), the article was not designated solely by a name recognized in an official compendium and had been fabricated from two or more ingredients,

and its label failed to bear a statement of the quantity or proportion of chloroform therein, since the statement "contains not more than ½ minim of Chloroform" was incorrect as applied to an article containing ⅛ minim of chloroform in each tablet.

DISPOSITION: September 30, 1948. Default decree of condemnation and destruction.

2592. Misbranding of Therm-Massage Infra-Red Heat Applicator. U. S. v. 288 Cartons * * *. (F. D. C. No. 23881. Sample No. 12116–K.)

LIBEL FILED: October 30, 1947, Eastern District of Pennsylvania.

ALLEGED SHIPMENT: On or about September 2, 1947, by Sibert & Co., from East Orange, N. J.

PRODUCT: 288 cartons each containing 1 *Therm-Massage Infra-Red Heat Applicator*, together with a circular bearing the same name, at West Lawn, Pa. Examination showed that the device consisted of two pieces of molded bakelite, one serving as the handle and the other containing an electrically heated coil.

NATURE OF CHARGE: Misbranding, Section 502 (a), the following statements on the carton label and in the circular were false and misleading since the device was not capable of fulfilling the promises of benefit stated and implied: (Carton) "Relieves Colds-Sinus Rheumatic Pains Muscular Aches & Pains Stiff Neck—Sore Throat Pains in Back * * * to improve circulation * * * Relieves Pain Quickly" and (circular enclosed in carton with device) "For Pain Relief * * * Infra Red Rays have the ability to penetrate tissue and bone to depth, with even diffusion of Heat throughout that depth * * * Heat Relieves Pain of almost any kind and soothes tortured aching nerves * * * This speeds up the body process of carrying off the poisons of fatigue and waste matter. It invigorates the entire system. It brings fresh food to the nerves and tissues. It stimulates your system to fight more vigorously those disease germs which find their way into the body. Stiff aching muscles become supple again * * * Pains in the Back * * * Also apply it to that area of the Spine directly adjacent or nearest to the area of pain * * * Headache * * * Relieves most headaches with startling speed, even Nervous Headaches in the cerebellum, or back of head * * * Muscular Aches & Pains * * * Penetrating Heat and Massage are the recognized agents which relax the muscles, relieve the pain and stimulate the blood circulation into carrying off those poisons of oxidation. Sinus * * * Aid nature in its' burden of carrying away the germ laden mucous secretions which congest the Sinus processes. Unblock those tiny canals. Colds * * * Therm-Massage aids in relieving discomfort and congestion. Stiff Neck * * * Sprains & Bruises * * * Therm-Massage can also be used to relieve Arthritis, Bursitis, Neuritis, Neuralgia, etc. * * * Heat relaxes the tiny muscles of the face, throat and neck, and thus aids in preventing the formation of wrinkles * * * speeding the removal and elimination of the waste products accumulated there, which so often are the real cause of sallow, muddy complexions and skin blemishes * * * Nature's way of preserving youth and beauty * * * scarcity of wrinkles * * *."

DISPOSITION: November 15, 1948. Sibert & Co., claimant, having consented to the entry of a decree, judgment of condemnation was entered and the product was ordered released under bond for relabeling, under the supervision of the Federal Security Agency.

2593. Misbranding of Thermophore devices. U. S. v. 20 * * *, etc. (F. D. C. No. 24349. Sample No. 14913–K.)

LIBEL FILED: February 26, 1948, Northern District of Illinois.

ALLEGED SHIPMENT: On or about October 6 and December 17, 1947, by the Battle Creek Equipment Co., from Battle Creek, Mich.

PRODUCT: 20 *Thermophore devices* at Chicago, Ill., together with a number of circulars entitled "Soothing Pain Relieving" and a number of booklets entitled "I can highly recommend." Examination showed that the device consisted of an electrically heated unit covered with white canvas duck and equipped with two white flannel covers.

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements in the labeling of the device were false and misleading since they represented and suggested that the device was effective in the relief of all types of pain and in the treatment of the condition causing such pains; that it was effective in the prevention and cure of respiratory infections; and that it was effective to promote health and to prevent insomnia. The device was not effective for such purposes.

DISPOSITION: January 7, 1949. Default decree of condemnation. It was ordered that the labeling be destroyed and that the devices then be delivered to a charitable institution or destroyed.

2594. Misbranding of Zerret Applicator devices. U. S. v. 9 * * *. (F. D. C. No. 24324. Sample No. 14906–K.)

LIBEL FILED: February 3, 1948, Eastern District of Wisconsin.

ALLEGED SHIPMENT: On or about November 20, 1947, by Mary Stanakis, from Chicago, Ill.

PRODUCT: 9 devices known as *Zerret Applicator* at Sheboygan, Sheboygan Falls, Kohler, New Holstein, Plymouth, and Manitowoc, Wis. Examination showed that the device consisted of two plastic hemispheres connected with a plastic rod and partially filled with moist cotton.

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements in circulars entitled "Directions for the Use of Zerret Applicator," "Why Zerret Works," "The Therapeutic Potency of Expanded Hydrogen Atoms," and "Ferguson's Zerret-Applicator" were false and misleading. The statements represented and suggested that the device was effective in the cure, mitigation, treatment, and prevention of diseases of man, in the alleviation of symptoms, and in normalizing the functions of the body of man; that it would be effective in the treatment of obesity, abnormal thinness, glandular malfunctioning, diarrhea, constipation, congestions, over-accumulations of fluids, over-contracture of musculature, and progress of old age; and that the device when used as directed would constitute a safe and appropriate treatment for such diseases and conditions. The article would not be effective for such diseases and conditions, and when used as directed it may delay appropriate treatment of serious diseases, resulting in serious or permanent injury or death to the user.

DISPOSITION: December 14, 1948. Mary Stanakis, claimant, having filed an answer denying that the device was misbranded, but subsequently having consented to the entry of a decree, judgment of condemnation was entered and it was ordered that two of the devices and their labeling be delivered to the Federal Security Agency for record and research purposes and that the remaining devices and their labeling be destroyed.

2595. Misbranding of Dainty Maid Service. U. S. v. 13 Sets * * *. (F. D. C. No. 25479. Sample No. 48003–K.)

LIBEL FILED: August 23, 1948, Middle District of Pennsylvania.

ALLEGED SHIPMENT: On or about June 4 and July 15, 1948, by Dainty Maid, Inc., from Middlefield, Conn.

PRODUCT: 13 sets of *Dainty Maid Service* at Camp Hill, Pa. Examination showed that each set consisted of one booklet entitled "Why Haven't We Women been told this Thing before," one small carton labeled "Return Flow Earigator" which contained one glass device, 1 1-pound jar labeled "Dainty Maid Hygenic Powder," 1 green rubber bag, 1 green rubber nozzle labeled in raised letters "Dainty Maid Colonator," 1 piece of green rubber tubing 52 inches long, 1 piece of green rubber tubing 4 inches long, 1 steel clamp, 1 plastic measuring cup, and a return flow syringe device.

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements in the booklet were false and misleading. These statements represented and suggested that cleansing the vagina would be effective in preventing loss of youthful looks, irritableness, rough and pimpled skins, wrinkles on a young face, headaches, backaches, fatigue, offensive body odor, internal uncleanliness, sallow skin, drawn face, prematurely gray hair, withered cheeks, wrinkles, scrawniness, other unlovely, visible signs of neglected inward hygiene, odorless discharges, and leucorrhea. The article would not be effective for the purposes represented and suggested.

DISPOSITION: November 5, 1948. Default decree of condemnation and destruction.

DRUGS FOR VETERINARY USE

2596. Adulteration and misbranding of Fox No. 1 Mineral Feed and misbranding of Poultrate, Fox Special No. 7, Vetrone, and Fox Triumph Swine Liquid. U. S. v. 17 Bags, etc. (F. D. C. No. 25079. Sample Nos. 25384–K to 25387–K, incl., 25389–K.)

LIBELS FILED: July 17, 1948, District of Minnesota.

ALLEGED SHIPMENT: On or about August 18, 1947, and January 23 and April 9, 1948, by Foxbilt Feeds, Inc., from Des Moines, Iowa.

PRODUCT: 17 100-pound bags of *Fox No. 1 Mineral Feed*, 55 100-pound bags of *Poultrate*, 10 1-pound cans of *Fox Special No. 7*, 1 1-gallon bottle of *Vetrone*, and 6 bottles of *Fox Triumph Swine Liquid* at Windom, Minn., together with a number of booklets entitled "Calling All Hens," received from Foxbilt Feeds, Inc., in May 1947, and a number of copies of a booklet entitled "Foxbilt Feeds," delivered by a salesman of the corporation during March 1948.

Analyses disclosed that the *Fox No. 1 Mineral Feed* was a stock feed containing charcoal, sulfur, calcium oxide or carbonate, and less than the declared amount of phosphorus; that the *Poultrate* was a stock feed containing protein, salt, iodine, and calcium carbonate and phosphate; and that the *Fox Special No. 7* was a tan aromatic powder. *The Vetrone* was indicated by its label to consist of ferric sulfate, cobalt sulfate, magnesium sulfate, ferrous sulfate, manganese sulfate, and aluminum sulfate, and the *Fox Triumph Swine Liquid* to consist of thymol, creosote, soda ash, sodium hydroxide, and salt.

NATURE OF CHARGE: *Fox No. 1 Mineral Feed.* Adulteration, Section 501 (c), the strength of the article differed from that which it was represented to possess, namely, "Phosphorus not less than 50%." Misbranding, Section 502 (a), the

labeling of the article contained false and misleading statements. The statements represented and suggested that the article was effective in the treatment of shoats and gilts, where digestive disorders exist; that it was effective for pig and stock hog conditioning; for all types of unthrifty and backward conditions; for pigs when they go off their feed; for all types of horses in a weakened run-down condition; and for all types of sheep; and, further, that it was effective in the treatment of out-of-condition animals and poultry, and for flushing out birds when in a run-down condition. The article would not be effective in the treatment of such diseases and conditions.

Poultrate. Misbranding, Section 502 (a), the labeling of the article contained statements and designs which were false and misleading. The statements and designs represented and suggested that the article was effective in the prevention and treatment of coccidiosis, worms, cholera, typhoid, colds, roup, tuberculosis, and blackhead of poultry. The article when used as directed would not be effective for such purposes.

Fox Special No. 7. Misbranding, Section 502 (b) (2), the article failed to bear a label containing an accurate statement of the quantity of the contents; Section 502 (e) (2), the label of the article failed to bear the common or usual name of each active ingredient; and, Section 502 (f) (1), the labeling of the article failed to bear adequate directions for use.

Vetrone. Misbranding, Section 502 (a), the labeling of the article contained false and misleading statements. The statements represented and suggested that the article was effective in the prevention and treatment of diseases of poultry, hogs, and dairy cows. The article would not be effective for such diseases.

Fox Triumph Swine Liquid. Misbranding, Section 502 (a), the can label of the article bore false and misleading statements. The statements represented and suggested that the article when used in connection with *Fox No. 1 Mineral Feed*, would be of value in the prevention and treatment of diseased conditions of swine and would be effective in alkalinizing the intestinal tract of swine. The article would not be of value or effective for such purposes.

DISPOSITION: November 10, 1948. Foxbilt Feeds, Inc., claimant, having consented to the entry of a decree, judgment of condemnation was entered and the products were ordered released under bond for reprocessing and relabeling, under the supervision of the Federal Security Agency.

2597. Misbranding of Calfurdine. U. S. v. 29 Bottles * * * (and 1 other seizure action). (F. D. C. Nos. 25359, 25515. Sample Nos. 28187–K, 29910–K.)

LIBELS FILED: August 23 and September 8, 1948, District of New Mexico.

ALLEGED SHIPMENT: By the Germ-O-Tone Laboratories, from Phoenix, Ariz. The product was shipped on or about December 16 and 24, 1947, and a number of circulars were delivered on or about December 15 and 31, 1947.

PRODUCT: *Calfurdine.* 58 bottles at Roswell, N. Mex., and 130 bottles and 17 jugs at Albuquerque, N. Mex., together with a number of circulars relating to the product entitled "Important Information Published For: Poultrymen Rabbitries Livestock Producers Pet & Game Bird Raisers and Fur Bearing Animal Farms." The bottles were in 8-ounce, 16-ounce, and 32-ounce sizes, and the jugs were in ½-gallon and 1-gallon sizes.

LABEL, IN PART: "Flowers of Sulfur . . . 0.09 Iodine . . . 0.04 Lime . . . 1.39 (Total Sulfur . . . 3.08) Calcium Thio-Sulphate . . . 0.68 Calcium Polysulphide . . . 2.31 Potassium nitrate . . . 0.79 Inert . . . 94.70."

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements on the label of the article and in the circulars were false and misleading since they represented and suggested that the article when used as directed was effective in the prevention and treatment of external and internal parasitic infestations and other diseased conditions of animals, whereas the article when used as directed would not be effective for such purposes.

DISPOSITION: September 28 and October 11, 1948. Default decrees of condemnation and destruction.

2598. Misbranding of poultry tonic. U. S. v. 9 Jars, etc. (F. D. C. No. 24312. Sample No. 14452–K.)

LIBEL FILED: February 3, 1948, Northern District of Illinois.

ALLEGED SHIPMENT: On or about November 21, 1947, by O. J. Mayfield, from Charles City, Iowa.

PRODUCT: 9 1-pound jars and 9 5-pound drums of *poultry tonic* at Arlington Heights, Ill. Analysis showed that the product consisted essentially of the ingredients declared on its label, namely, iron oxide, arsenic trioxide, copper sulfate, and small amounts of aluminum, manganese, and cobalt sulfates, magnesium carbonate, potassium iodide, and plant ingredients.

LABEL, IN PART: "Dr. Mayfield Poultry Tonic * * * Manufactured Under Direction of O. J. Mayfield, D. V. M., Charles City, Iowa."

NATURE OF CHARGE: Misbranding, Section 502 (a), the following label statements were false and misleading: "POULTRY TONIC Use as a tonic for chicks and poults—as an aid in the control of Monelia sp. moulds." The statements represented and suggested that the article was a poultry tonic and was effective as a tonic for chicks and poults, and that the article was effective to inhibit and prevent the growth of Monelia species molds and was effective in the treatment of mycosis due to Monelia species molds. The article was not a poultry tonic and was not effective for the purposes stated and implied.

DISPOSITION: November 5, 1948. Default decree of condemnation and destruction.

2599. Misbranding of Chexit. U. S. v. 11 Bottles, etc. (F. D. C. No. 24903. Sample No. 20501–K.)

LIBEL FILED: On or about July 6, 1948, Western District of Missouri.

ALLEGED SHIPMENT: On or about March 8, 1948, by United Farmers Exchange, from Council Bluffs, Iowa.

PRODUCT: 11 3-pound bottles and 46 1-pound bottles of *Chexit* at Excelsior Springs, Mo. Analysis showed that the product consisted chiefly of calcium carbonate, powdered nux vomica, poke root, ginger, fenugreek, and potassium iodide.

LABEL, IN PART: "Chexit for Livestock Demulcent Anti-Acid Mixture."

NATURE OF CHARGE: Misbranding, Section 502 (a), the name of the article and certain statements on its label were false and misleading since such name and statements represented and suggested that the article when used as directed was effective to check disease conditions of calves, lambs, colts, kids, sows with suckling pigs, milch cows, and steers, and that the article was a demulcent tonic and a tonic to the appetite of animals. The article when used as directed was not effective to check disease conditions of the animals mentioned, and it was not a demulcent tonic nor a tonic to the appetite of animals.

DISPOSITION: October 26, 1948. Default decree of destruction.

2600. Misgranding of General Hog-Liquid. U. S. v. 5 Drums, etc. (F D. C. No. 24942. Sample No. 25222–K.)

LIBEL FILED: July 6, 1948, Northern District of Iowa.

ALLEGED SHIPMENT: On or about March 25, 1948, by the General Veterinary Co., from Omaha, Nebr.

PRODUCT: 5 5-gallon drums, 5 3-gallon drums, and 5 2-gallon drums of *General Hog-Liquid* at Carroll, Iowa.

LABEL, IN PART: "General Hog-Liquid * * * Ingredients Calcium Phosphate, Beechwood Creosote, Potassium Iodide, Extract of Glycyrrhiza, Sodium Hydroxide, Copper Sulphate, Creosote U. S. P., Water 10.5%. Extract of Nux Vomica, giving one quart of medicine 0.10 Grams of strychnine. Solution of Potassium Arsenite 59.5% (giving one quart of medicine 60 gr. of arsenic)."

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements on the label of the article were false and misleading since they represented and suggested that the article was effective in the treatment of some intestinal infections and diarrhea of hogs, whereas the article was not effective for such purposes.

DISPOSITION: August 6, 1948. Default decree of condemnation and destruction.

INDEX TO NOTICES OF JUDGMENT D. D. N. J. NOS. 2551 TO 2600

PRODUCTS

[1] (2579, 2582) Prosecution contested.
[2] (2580) Prosecution contested. Contains opinions of the courts.
[3] (2555) Seizure contested. Contains finding of fact and conclusions of law.
[4] (2573) Contempt of court proceedings. Contains opinions of the court.
[5] (2578) Prosecution contested. Contains opinion of the court.

SHIPPERS, MANUFACTURERS, AND DISTRIBUTORS

[1] (2579, 2582) Prosecution contested.
[2] (2580) Prosecution contested. Contains opinions of the courts.
[3] (2555) Seizure contested. Contains findings of fact and conclusions of law.
[4] (2573) Contempt of court proceedings. Contains opinions of the court.
[5] (2578) Prosecution contested. Contains opinion of the court.
[6] (2553) Permanent injunction issued.

[1] (2579, 2582) Prosecution contested.
[2] (2580) Prosecution contested. Contains opinions of the courts.
[4] (2573) Contempt of court proceedings. Contains opinions of the court.
[5] (2578) Prosecution contested. Contains opinion of the court.

[3] (2555) Seizure contested. Contains findings of fact and conclusions of law.
[4] (2573) Contempt of court proceedings. Contains opinions of the court.

ERRATUM

D. D. N. J. 2475, p. 166. Under PRODUCT, line 2, delete "grams" and substitute "grains."

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FEDERAL SECURITY AGENCY

FOOD AND DRUG ADMINISTRATION

NOTICES OF JUDGMENT UNDER THE FEDERAL FOOD, DRUG, AND COSMETIC ACT

[Given pursuant to section 705 of the Food, Drug, and Cosmetic Act]

2601–2650

DRUGS AND DEVICES

The cases reported herewith were instituted in the United States district courts by the United States attorneys acting upon reports submitted by direction of the Federal Security Administrator.

J. DONALD KINGSLEY, *Acting Administrator, Federal Security Agency.*

WASHINGTON, D. C., *May 31, 1949.*

CONTENTS*

*For omission of, or unsatisfactory, ingredients statements, see Nos. 2601, 2606, 2607, 2634, 2641, 2646–2648; failure to bear a label containing an accurate statement of the quantity of the contents, Nos. 2607, 2641, 2647, 2648; failure to bear a label containing the name and place of business of the manufacturer, packer, or distributor, Nos. 2602, 2607, 2648; cosmetics, actionable under the drug provisions of the Act, Nos. 2641–2643.

839988—49——1

DRUGS AND DEVICES ACTIONABLE BECAUSE OF POTENTIAL DANGER WHEN USED ACCORDING TO DIRECTIONS

2601. Misbranding of Lawrence's Iron and Liver Capsules, Lawrence's Mineral Tablets, Lawrence's Laxative No. 1 Tablets, Lawrence's Meth-Phos Pills, Lawrence's Nervo Tablets, Vitamin C Tablets, Lawrence's Vitamin E Capsules, and Lawrence's Heavy Base Ointment. U. S. v. Lawrence V. Devine (Lawrence Drug Co.). Plea of guilty. Fine, $170. (F. D. C. No. 24282. Sample Nos. 20304–K, 20306–K to 20309–K, incl., 20311–K to 20313–K, incl.)

INFORMATION FILED: January 21, 1949, Western District of Missouri, against Lawrence V. Devine, trading as the Lawrence Drug Co., at Kansas City, Mo.

ALLEGED SHIPMENT: On or about August 28, 1947, from the State of Missouri into the State of Oklahoma.

LABEL, IN PART: "Capsules Iron & Liver * * * Each capsule contains: Ferrous Sulfate U. S. P. 3⅗ gr. Liver concentrate equiv. to 7 gr. Vitamin B–1 . . . 331 U. S. P. Units Vitamin B–2 . . . 500 Gamma Niacinamide . . . 5.0 mg. Calcium Pantothenate . . . 1 mg."; "Lawrence's High Potency Mineral Tablets * * * Containing: Di-Calcium Phosphate, Iron, Copper Peptonate, Manganese Carbonate, Zinc Oxide, Magnesium Oxide, and Potassium Iodide"; "Lawrence's famous Laxative No. 1 100 Brown Tablets * * * Bile Salts compound . . . 1 gr. Papain . . . 2 grs. Phenolthalene . . . ½ gr. Ext. Nux Vomica . . . 1/16 gr. Ext. Cascara Sagrada . . . ½ gr. Oleoresin Capsicum . . . 1/40 gr."; "Lawrence's Meth-Phos Pills * * * Each tablet contains: Hexamethylenamine . . . 5 grs. Sodium Acid Phosphate . . . 5 grs."; "Lawrence's Nervo Tablets * * * Each tablet contains: Sodium Bromide . . . 5 grs. Potassium Bromide . . . 5 grs. Amonium Bromide . . . 5 grs."; Vitamin 'C' (Ascorbic Acid) Tablets 100 Mg. Each tablet Contains: 100 Mg. of Vitamin C U.S.P. equivalent to 2,000 U.S.P. units of Vitamin C (Ascorbic Acid)."; "Capsules Vitamin E Natural Mixed Tocopherols"; and "Lawrence's Improved Heavy Base Ointment." Analysis of the ointment showed that it contained chiefly zinc oxide.

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements appearing on the labels of the articles (other than the *Lawrence's Nervo Tablets*) and in an accompanying booklet entitled "Lawrence's 1947 Medical Catalogue and Little Doctor Book" represented and suggested that the articles were preferred by medical doctors;

That the *Lawrence's Iron and Liver Capsules* would be efficacious in the cure, mitigation, and treatment of anemia, would help to build up the blood, and would increase one's strength and vitality;

That the *Lawrence's Mineral Tablets* were a potent and rich source of minerals and would be efficacious in the cure, mitigation, and treatment of bronchial asthma and in healing the mucous lining of the bronchioles;

That the *Lawrence's Laxative No. 1 Tablets* would stimulate the liver and thin the bile and act as a gall bladder stimulant; that they would wake-up the liver; that they would be efficacious in the treatment of a sluggish, nonfunctioning liver and a sluggish gall bladder; that they would be efficacious in the cure, mitigation, and treatment of spots before the eyes, dizziness, indigestion, bleching, colitis, pain over the gall bladder, inability to eat heavy or

fatty foods, gas, and bitter sour stomach; that the use of the article plus careful attention to the colon would save one from having an operation; and that its use in conjunction with colonic irrigations would heal a sluggish liver and a bad gall bladder and would give relief to one with a sluggish liver and a bad gall bladder;

That the *Lawrence's Meth-Phos Pills* would act as a stimulant and a diuretic to the kidneys; that they would be efficacious in the cure, mitigation, and treatment of bladder urinary irritation, frequent and burning urination, difficulty in passing urine, occasional backache, puffiness under the eyes, swelling of the ankles, low backache, frequent urination at night, scanty passage of urine, lazy kidneys, and kidney troubles; that they would correct sluggish kidney action; that they were used frequently by urologists in the treatment of sluggishness of the kidneys and infection in the urinary tract; and that they would be efficacious in the treatment of sluggishness of the kidneys and infection in the urinary tract.

That the *Vitamin C Tablets* would be efficacious in the cure, mitigation, and treatment of infections, colds, flu, pimples, hives, eczema, hay fever, asthma, and boils, and would be efficacious as an anti-allergic;

That the *Lawrence's Vitamin E Capsules* would be efficacious to restore loss of vigor and vitality and would be efficacious in the treatment and prevention of nerve weakness, paralysis, gray hair, and sterility;

That the *Lawrence's Heavy Base Ointment* would be efficacious in the cure, mitigation, and treatment of leg ulcers, varicose veins, and poor circulation.

The above statements were false and misleading since the products were not preferred by doctors; the *Lawrence's Mineral Tablets* were not a potent and rich source of minerals; and the products would not fulfill the promises of benefit stated and implied.

Further misbranding, Section 502 (f) (2), the labeling of the *Lawrence's Laxative No. 1 Tablets* failed to bear a warning that they should not be used in the presence of abdominal pain, nausea, vomiting, and other symptoms of appendicitis.

Lawrence's Nervo Tablets. Misbranding, Section 502 (f) (2), the labeling of the drug failed to bear such adequate warnings against use in those pathological conditions where its use may be dangerous to health and against unsafe dosage and duration of administration, in such manner and form as are necessary for the protection of users, in that the drug contained bromides, the use of which may be dangerous to the health of persons with kidney disease, and frequent and continued use of a drug containing bromides may lead to mental derangement, skin eruptions, and other serious effects; and the labeling of the product failed to bear warnings of such dangers.

Further misbranding, Section 502 (j), the *Lawrence's Nervo Tablets* were dangerous to health when used in the dosage and with the frequency and duration prescribed, recommended, and suggested in their labeling, "Adult Dose: Take one tablet 2 or 3 times a day," since the labeling provided for the consumption of an excessive and dangerous amount of bromides.

Further misbranding, section 502 (e) (2), the *Lawrence's Heavy Base Ointment* was not designated solely by a name recognized in an official compendium, and its label failed to bear its common or usual name, "Zinc Oxide Ointment."

DISPOSITION: February 2, 1949. A plea of guilty having been entered, the court imposed a fine of $170.

2602. Misbranding of Gomco ring pessaries. U. S. v. 17 Devices * * * (and 1 other seizure action). (F. D. C. Nos. 25753, 25764. Sample Nos. 27462–K, 27464–K, 37644–K.)

LIBELS FILED: On or about September 13 and 30, 1948, Eastern District of Missouri and District of Oregon.

ALLEGED SHIPMENT: On or about March 30, May 24, and July 30, 1948, by the Gomco Surgical Manufacturing Corp., from Buffalo, N. Y.

PRODUCT: *Gomco ring pessaries.* 17 devices at St. Louis, Mo., and 20 devices at Klamath Falls, Oreg., together with a number of circulars entitled "Gomco Intrauterine Ring." Examination showed that the device was a metallic ring, approximately one inch in diameter, which was fashioned from a coiled spring.

NATURE OF CHARGE: Misbranding, Section 502 (j), the device was dangerous to health when used with the frequency and duration recommended and suggested in the circulars, namely, "It may be left in the uterus indefinitely. Cases have been reported in which the ring has been left in position for six years, without removal and with no ill effect. Pathological Tests Give No Indications of Malignancy. We would suggest however that the physician withdraw and place the Gomco Intra-Uterine Ring yearly * * * Technic: (As Suggested by Haire) 'The Ring Pessary should be inserted during menstrual period in order that one may be certain that patient is not already pregnant. The patient is placed in the lithotomy position, a vaginal speculum is inserted by means of special introducer. There is usually no pain following its introduction and no pain at the periods. Even in cases where menstruation has been painful, previously, the presence of the ring seems to diminish it. Technic of Gomco Intra-Uterine Ring. Gomco Intra-Uterine Ring in Uterus (Diagrams showing method of inserting Ring and its position in the Uterus)."

Further misbranding, Section 502 (a), the statements in the circulars "The Gomco Intra-Uterine Ring is used where a * * * safe procedure for contraception is indicated" was false and misleading since the device could not be safely used under any conditions; and, Section 502 (b) (1), the device failed to bear a label containing the name and place of business of the manufacturer, packer, or distributor.

DISPOSITION: October 14 and November 5, 1948. Default decrees of condemnation and destruction.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF FAILURE TO BEAR ADEQUATE DIRECTIONS OR WARNING STATEMENTS*

2603. Misbranding of ring pessaries. U. S. v. 4 Medium ring pessaries, etc. (F. D. C. No. 25742. Sample Nos. 25869–K, 25870–K.)

LIBEL FILED: September 10, 1948, District of Minnesota.

ALLEGED SHIPMENT: On or about March 1, 1946, and January 29 and May 3, 1948, by the Gomco Surgical Manufacturing Corp., from Buffalo, N. Y.

PRODUCT: 4 medium and 3 small *ring pessaries* at Minneapolis, Minn. Examination showed that the device was a metallic ring, approximately one inch in diameter which was fashioned from a coiled spring.

*See also Nos. 2601, 2646.

NATURE OF CHARGE: Misbranding, Section 502 (f) (1), the labeling of the article failed to bear adequate directions for use for the purpose for which it was intended.

DISPOSITION: January 6, 1949. Default decree of destruction.

2604. Misbranding of Zon-A-Wave Ozone Generator. U. S. v. 12 Devices, etc. (F. D. C. No. 26003. Sample No. 32306–K.)

LIBEL FILED: December 9, 1948, Northern District of California.

ALLEGED SHIPMENT: On or about September 8, 1948, from Portland, Oreg.

PRODUCT: 12 devices, some of which were labeled "Zon-A-Wave Ozone Generator" and others which were labeled "Portable Ozone Applicator," in the possession of Mrs. Etta H. Gehlen, San Jose, Calif., and certain other persons in Los Gatos, San Jose, and Oakland, Calif., on rental from Mrs. Gehlen. 5,000 pamphlets entitled "Ozone Health Center" and 5 display cards entitled "Pure Ozone is being generated" were also in the possession of Mrs. Gehlen. The pamphlets and display cards were printed in San Jose, on instructions of Mrs. Gehlen. Examination showed that the device was an electrical device which generated ozone.

NATURE OF CHARGE: Misbranding, Section 502 (a), the pamphlets and display cards contained statements which represented and suggested that the devices were effective in the treatment of rheumatism, sinus trouble, neuritis, colds, influenza, stomach trouble, osteomyelitis caused by scarlet fever, severe pain, cough left as an effect of pneumonia, infection, sprained ankle, lame back, varicose veins, chest colds, severe abdominal pains caused by gallstone attack, headache, sinus pains, milk leg, high fever, paralysis from multiple neuritis, continual pain, arthritis, and other kindred ailments, impurities in the blood, and ulcers; that the devices would prevent diseases including tonsillitis, sore throat, colds, headache, stomach-ache, ear-ache, tooth-ache, indigestion, fever, la grippe, and pneumonia; and that the devices would increase efficiency. The devices were not effective in the treatment of the symptoms, diseases, and conditions stated and implied; they would not prevent the diseases and conditions named; and they would not increase efficiency.

Further misbranding, Section 502 (f) (1), the devices bore no directions for use. The devices were misbranded while held for sale after shipment in interstate commerce.

DISPOSITION: December 14, 1948. Default decree of condemnation. One device and several copies of the pamphlet and display card were ordered delivered to the Food and Drug Administration, for exhibition in its museum at Washington, D. C., and the remainder of the devices, pamphlets, and display cards were ordered destroyed.

2605. Adulteration and misbranding of elixer of three bromides, tincture of opium camphorated (paregoric), syrup of potassium guaiacolsulfonate, and elixir of terpin hydrate and codeine. U. S. v. David M. Leff (Merit Laboratories Co.). Plea of nolo contendere. Fine, $700. (F. D. C. No. 25581. Sample Nos. 32–K, 33–K, 52–K, 10425–K, 15156–K.)

INFORMATION FILED: January 25, 1949, Eastern District of Pennsylvania, against David M. Leff, trading as the Merit Laboratories Co., Philadelphia, Pa.

ALLEGED SHIPMENT: Between the approximate dates of February 4 and March 2, 1948, from the State of Pennsylvania into the States of South Carolina, New York, and Michigan.

NATURE OF CHARGE: *Elixir of Three Bromides.* Adulteration, Section 501 (b), the article purported and was represented as "Three Bromides Elixir," a drug the name of which is recognized in the National Formulary, an official compendium, and its strength differed from the official standard since each 100 cc. of the article contained less than 23 grams of total bromides, and the difference in strength of the article from the standard was not stated on its label.

Misbranding, Section 502 (a), the label statements "Elixir of Three Bromides N. F. * * * Each 100 cc Contains 8 Gm Ammoniated Bromide * * * 8 Gm Potassium Bromide * * * 8 Gm Sodium Bromide" were false and misleading since the article did not conform to the specifications of the National Formulary and each 100 cc. of the article contained less than 24 grams of bromides.

Tincture of opium camphorated (paregoric). Adulteration, Section 501 (b), the article purported to be "Camphorated Opium Tincture," a drug the name of which is recognized in the United States Pharmacopoeia, an official compendium, and its strength differed from the official standard since each 100 cc. of the article yielded more than 45 mg. of anhydrous morphine and the difference in strength of the article from the standard was not stated on its label. Misbranding, Section 502 (a), the label statement "Each fluid ounce represents Opium powdered 1.83 gr." was false and misleading since the statement represented that each fluid ounce of the article contained the therapeutically active constituent of powdered opium, namely, anhydrous morphine, in an amount not more than is present in 1.83 grains of powdered opium, whereas each fluid ounce of the article contained the therapeutically active constitutent of powdered opium in a larger amount than is present in 1.83 grains of powdered opium.

Syrup of potassium guaiacolsulfonate. Adulteration, Section 501 (b), the article purported to be and was represented as "Potassium Guaiacolsulfonate Syrup," a drug the name of which is recognized in the National Formulary, an official compendium, and its strength differed from the official standard since each 1,000 cc. of the article contained less than 75 grams of potassium guaiacolsulfonate and the difference in the strength of the article from the standard was not stated on its label. Misbranding, Section 502 (a), the label statement "Syrup of Potassium Guaiacolsulfonate N. F. Each 100 cc. represents Potassium Guaiacolsulfonate 7.5 gm." was false and misleading since the article did not conform to the specification of the National Formulary and each 100 cc. of the article contained less than 7.5 grams of potassium guaiacolsulfonate.

Elixir of terpin hydrate and codeine. Adulteration, Section 501 (b), the article purported to be and was represented as "Terpin Hydrate and Codeine Elixir," a drug the name of which is recognized in the National Formulary, an official compendium, and its strength differed from the official standard since it contained less terpin hydrate and less codeine than required by the standard and the difference in the strength of the article from the standard was not stated on its label. Misbranding, Section 502 (a), the label statements "Elixir Terpin Hydrate and Codeine N. F. * * * Active constituents in each 100 cc. Terpin Hydrate 1.7 gms. Codeine alkaloid 0.2 gms.," were false and misleading since the article did not conform to the specifications of the National Formulary and each 100 cc. of the article contained less than 1.7 grams of terpin hydrate and less than 0.2 grams of codeine alkaloid.

Further misbranding, Section 502 (f) (1), the labeling of all of the articles failed to bear adequate directions for use since there was no statement in the labeling of any condition, disease, or function for which the articles were to be used.

DISPOSITION: February 16, 1949. A plea of nolo contendere having been entered, the court imposed a fine of $700.

2606. Misbranding of Dee-Lay Caps. U. S. v. The Duncan Co. Plea of guilty. Fine, $100. (F. D. C. No. 25564. Sample No. 20887–K.)

INFORMATION FILED: November 17, 1948, Western District of Oklahoma, against The Duncan Co., a partnership, trading under the name of the Dee-Lay Co., at Oklahoma City, Okla.

ALLEGED SHIPMENT: On or about December 30, 1947, from the State of Oklahoma into the State of Kansas.

PRODUCT: *Dee-Lay Caps.* Analysis showed that the product consisted chiefly of capsules containing camphor, ferrous sulfate, with capsicum and aloes indicated, and tablets containing calomel with plant material indicated.

NATURE OF CHARGE: Misbranding, Section 502 (a), the label statement "Dee-Lay Caps * * * Recommended for the relief of delayed menstration caused from Colds, Nervousness or Over Exposure" was false and misleading since the article would not be efficacious in the treatment of delayed menstruation and would not be efficacious for the relief of delayed menstruation caused from colds, nervousness, and over exposure. Further misbranding, Section 502 (e) (2), the article was not designated solely by a name recognized in an official compendium and was fabricated from two or more ingredients, and the tablets of the article contained the ingredient, calomel, a derivative of mercury; and the label of the article did not bear a statement showing the substance from which the ingredient was derived and the fact that the ingredient was derived from mercury; and, further, the label did not bear a statement of the quantity or proportion of calomel contained in the tablets. Further misbranding, Section 502 (f) (2), the article was a laxative and its labeling failed to bear a warning that it should not be used when abdominal pain (stomach-ache, cramps, and colic), nausea, vomiting (stomach sickness), or other symptoms of appendicitis are present, and the labeling of the article also failed to warn that frequent or continued use may result in dependence upon laxatives to move the bowels.

DISPOSITION: January 4, 1949. A plea of guilty having been entered, the court imposed a fine of $100.

2607. Misbranding of orchic substance and spleen liquid. U. S. v. 187 Vials, etc. (F. D. C. No. 25850. Sample Nos. 7492–K, 7493–K.)

LIBEL FILED: October 14, 1948, Western District of New York; amended libel filed November 3, 1948.

ALLEGED SHIPMENT: On or about September 1, 1948, by Bruce Laboratories, Inc., from Trenton, N. J.

PRODUCT: 187 30-cc. size vials of *orchic substance* and 170 25-cc. size vials of *spleen liquid* at Buffalo, N. Y. There were no labels upon the immediate containers of the articles. In the shipping cartons were handwritten sheets bearing the following: "Control #484 Orchic Substance Ziegler order #2221 192 Total" and "Control #485 Spleen Liquid Ziegler order #2221 Total No. of Bottles 175."

NATURE OF CHARGE: Misbranding, Section 502 (b) (1), the articles failed to bear labels containing the name and place of business of the manufacturer, packer, or distributor; Section 502 (b) (2), they failed to bear labels containing an accurate statement of the quantity of the contents; Section 502 (e) (1), the labels of the articles failed to bear the common or usual names of the articles,

namely, *orchic substance* or *spleen liquid;* and, Section 502 (f) (1), the labelings of the articles failed to bear adequate directions for their use.

DISPOSITION: November 23, 1948. Default decree of condemnation and destruction.

2608. Misbranding of Nue-Ovo. U. S. v. 4 Units * * *. (F. D. C. No. 25940. Sample No. 25635–K.)

LIBEL FILED: November 18, 1948, Southern District of Iowa.

ALLEGED SHIPMENT: On or about October 21, 1948, by the Research Laboratories, from Portland, Oreg.

PRODUCT: 4 units, each containing 3 1-pint bottles, of *Nue-Ovo* at Ames, Iowa.

LABEL, IN PART: "Nue-Ovo * * * Active Ingredients: An aqueous extraction of Plume Thistle, Burdock, Quasia, Sage, Cinnamon, Horehound, Ginseng, Calamus, Dandelion, Althea, Kola Nut, Sodium Salicylate Cascara Licorice, Vitamin B_1."

NATURE OF CHARGE: Misbranding, Section 502 (f) (1), the labeling of the article failed to bear adequate directions for use since the labeling failed to reveal the diseases or conditions of the body for which the article, when used as directed, would be effective.

DISPOSITION: February 12, 1949. Default decree of condemnation and destruction.

2609. Misbranding of herbs. U. S. v. 168 Boxes * * *. (F. D. C. No. 25864. Sample No. 48073–K.)

LIBEL FILED: October 18, 1948, Eastern District of Pennsylvania.

ALLEGED SHIPMENT: On or about August 11, 1948, from Cincinnati, Ohio.

PRODUCT: 168 boxes of *herbs at* Philadelphia, Pa., in the possession of Felix Hawkins, Jr., Sales of the product were made on the basis of lectures given on a street corner by Jesse White Eagle and Burt Carman, on behalf of Felix Hawkins, Jr. The charge of misbranding is based on their oral representations.

LABEL, IN PART: "Herbs Active Ingredients Cascara, Senna, Mandrake, Also Contains Wild Cherry, Quassia, Yam, Celery Seed, Stillingia, Poke Root and Licorice."

NATURE OF CHARGE: Misbranding, Section 502 (f) (1), the labeling of the article failed to bear adequate directions for use in the treatment of menstrual difficulties, sexual impotency, poor eyesight, dental troubles, stomach trouble, kidney trouble, run-down condition, nervousness, rheumatism, and arthritis, which are the diseases, symptoms, and conditions for which the article was intended. The product was misbranded while held for sale after shipment in interstate commerce.

DISPOSITION: November 24, 1948. Default decree of condemnation and destruction.

DRUGS ACTIONABLE BECAUSE OF CONTAMINATION WITH FILTH

2610. Adulteration of horehound herb. U. S. v. 4½ Bales * * *. (F. D. C. No. 25906. Sample No. 45449–K.)

LIBEL FILED: November 5, 1948, District of Minnesota.

ALLEGED SHIPMENT: On or about June 4 and 20, 1947, from New York, N. Y.

PRODUCT: 4½ bales each containing approximately 800 pounds, of *horehound herb* at Minneapolis, Minn.

NATURE OF CHARGE: Adulteration, Section 501 (a) (1), the article consisted in whole or in part of a filthy substance by reason of the presence of insects and rodent excreta. The article was adulterated while held for sale after shipment in interstate commerce.

DISPOSITION: February 2, 1949. Default decree ordering that the product be destroyed unless denatured and disposed of for use as animal feed.

2611. Adulteration of quince seed. U. S. v. 11 Bags * * *. (F. D. C. No. 25812. Sample No. 9574–K.)

LIBEL FILED: October 11, 1948, Southern District of New York.

ALLEGED SHIPMENT: On or about April 26, 1946, from Iran.

PRODUCT: 11 118-pound bags of *quince seed* at New York, N. Y.

NATURE OF CHARGE: The article was adulterated while held for sale after shipment in interstate commerce under Section 501 (a) (1), in that it consisted in whole or in part of a filthy substance by reason of the presence of insects.

DISPOSITION: November 1, 1948. Default decree of condemnation and destruction.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF DEVIATION FROM OFFICIAL OR OWN STANDARDS*

2612. Adulteration of physiological salt solution. U. S. v. 776 Vials * * *. (F. D. C. No. 25798. Sample No. 19492–K.)

LIBEL FILED: October 4, 1948, Eastern District of Kentucky.

ALLEGED SHIPMENT: On or about July 15, 1948, by the Hyland Laboratories, from Los Angeles, Calif.

PRODUCT: 776 100-cc. vials of *physiological salt solution* at Lexington, Ky. The vials had a rubber cap which indicated that the product was intended for intravenous or intramuscular use.

LABEL, IN PART: "Physiological Salt Solution (Isotonic Solution of Sodium Chloride)."

NATURE OF CHARGE: Adulteration, Section 501 (b), the article purported to be and was represented as "Sterile Isotonic Sodium Chloride Solution for Parenteral Use," a drug the name of which is recognized in the United States Pharmacopoeia, an official compedium, and its quality and purity fell below the official standard since it was contaminated with undissolved material.

DISPOSITION: October 27, 1948. Default decree of condemnation and destruction.

2613. Adulteration of sodium thiosulfate ampuls. U. S. v. 275 Ampuls * * *. (F. D. C. No. 25763. Sample No. 1052–K.)

LIBEL FILED: September 29, 1948, Southern District of Florida.

ALLEGED SHIPMENT: On or about July 21, 1948, from New Rochelle, N. Y.

PRODUCT: 275 10-cc. ampuls of *sodium thiosulfate* at Miami, Fla.

*See also Nos. 2605, 2648.

LABEL, IN PART: "10cc Ampul Sodium Thiosulfate * * * For Intravenous Use."

NATURE OF CHARGE: The article was adulterated while held for sale after shipment in interstate commerce under Section 501 (b), in that it purported to be and was represented as "Sodium Thiosulfate Ampuls," a drug the name of which is recognized in the National Formulary, an official compendium, and its quality and purity fell below the official standard since it was contaminated with undissolved material.

DISPOSITION: November 12, 1948. Default decree of forfeiture and destruction.

2614. Adulteration of sodium thiosulfate ampuls. U. S. v. 136 Boxes * * *. (F. D. C. No. 25629. Sample No. 43450–K.)

LIBEL FILED: September 15, 1948, Northern District of Illinois.

ALLEGED SHIPMENT: On or about April 20, 1948, by the Sherman Laboratories, from Detroit, Mich.

PRODUCT: 136 boxes, each containing 5 10-cc. ampuls, of *sodium thiosulfate* at Chicago, Ill.

NATURE OF CHARGE: Adulteration, Section 501 (b), the article purported to be and was represented as "Sodium Thiosulfate Ampuls," a drug the name of which is recognized in the National Formulary, an official compendium, and its quality and purity fell below the official standard since it was contaminated with viable micro-organisms and undissolved material.

DISPOSITION: March 28, 1949. Default decree of condemnation and destruction.

2615. Adulteration of sodium salicylate and sodium iodide with colchicine. U. S. v. 50 Vials * * *. (F. D. C. No. 25738. Sample No. 19572–K.)

LIBEL FILED: October 27, 1948, Eastern District of Tennessee.

ALLEGED SHIPMENT: On or about September 15, 1948, by the Direct Sales Co., Inc., from Buffalo, N. Y.

PRODUCT: 50 250-cc. vials of *sodium salicylate and sodium iodide with colchicine* at Chattanooga, Tenn.

NATURE OF CHARGE: Adulteration, Section 501 (b), the article purported and was represented as "Sodium Salicylate and Iodide with Colchicine Ampuls," a drug the name of which is recognized in the National Formulary, an official compendium, and its quality and purity fell below the official standard since it was contaminated with undissolved material.

DISPOSITION: On or about December 31, 1948. Default decree of condemnation and destruction.

2616. Adulteration of aminophylline. U. S. v. 375 Ampuls * * *. (F. D. C. No. 25702. Sample No. 15559–K.)

LIBEL FILED: October 12, 1948, Eastern District of Michigan.

ALLEGED SHIPMENT: On or about September 15, 1948, by the Direct Sales Co., Inc., from Buffalo, N. Y.

PRODUCT: 375 10-cc. size ampuls of *aminophylline* at Detroit, Mich.

LABEL, IN PART: "Each 10 cc represents Aminophylline U. S. P. 3¾ Grs. * * * For Intravenous Use."

NATURE OF CHARGE: Adulteration, Section 501 (b), the article purported to be and was represented as "Aminophylline Injection," a drug the name of which is recognized in the United States Pharmacopoeia, an official compendium, and its quality and purity fell below the official standard since it was contaminated with undissolved material.

DISPOSITION: November 12, 1948. Default decree of condemnation and destruction.

2617. Adulteration of calcium gluconate. U. S. v. 1,043 Ampuls * * *. (F. D. C. No. 25913. Sample Nos. 29360–K, 29361–K.)

LIBEL FILED: November 8, 1948, District of Colorado.

ALLEGED SHIPMENT: On or about March 2 and September 29, 1948, by the Carroll Dunham Smith Pharmacal Co., from Kansas City, Mo.

PRODUCT: 1,043 10-cc. ampuls of *calcium gluconate* at Colorado Springs, Colo.

NATURE OF CHARGE: Adulteration, Section 501 (b), the article purported to be and was represented as "Calcium Gluconate Injection," a drug the name of which is recognized in the United States Pharmacopoeia, an official compendium, and its quality and purity fell below the official standard since it was contaminated with undissolved material.

DISPOSITION: December 23, 1948. Default decree of condemnation and destruction.

2618. Adulteration of thiamine hydrochloride. U. S. v. 26 Vials * * *. (F. D. C. No. 25765. Sample No. 10781–K.)

LIBEL FILED: September 21, 1948, Eastern District of New York.

ALLEGED SHIPMENT: On or about April 21, 1948, from Newark, N. J.

PRODUCT: 26 30-cc. vials of *thiamine hydrochloride* at Brooklyn, N. Y.

LABEL, IN PART: "Sterile Multiple Dose Vial Thiamine Hydrochloride Vitamin B_1, * * * intramuscularly or intravenously."

NATURE OF CHARGE: Adulteration, Section 501 (b), the article purported to be and was represented as "Thiamine Hydrochloride Injection," a drug the name of which is recognized in the United States Pharmacopoeia, an official compendium, and its quality and purity fell below the official standard since it was contaminated with undissolved material. The article was adulterated while held for sale after shipment in interstate commerce.

DISPOSITION: December 15, 1948. Default decree of condemnation and destruction.

2619. Adulteration of solution of vitamin B complex. U. S. v. 17 Vials * * *. (F. D. C. No. 25752. Sample No. 30143–K).

LIBEL FILED: September 16, 1948, District of Arizona.

ALLEGED SHIPMENT: On or about July 26, 1948, by the American Bio-Chemical Corp., from Los Angeles, Calif.

PRODUCT: 17 30-cc. vials of *solution of vitamin B complex* at Phoenix, Ariz.

LABEL, IN PART: "Sterile Solution Some Factors of Vitamin B Complex."

NATURE OF CHARGE: Adulteration, Section 501 (c), the purity and quality of the article fell below that which it purported and was represented to possess, namely, "Sterile Solution Some Factors of Vitamin B Complex * * * For intravenous or intramuscular use," since the article contained undissolved

material, whereas an article which is represented for intravenous use should be substantially free of any undissolved material.

DISPOSITION: November 19, 1948. Default decree of condemnation and destruction.

2620. Adulteration and misbranding of Congo red solution. U. S. v. 7 Cartons, etc. (and 1 other seizure action). (F. D. C. Nos. 25745, 25746. Sample Nos. 5179–K, 5372–K, 5373–K.)

LIBELS FILED: September 10, 1948, District of Massachusetts.

ALLEGED SHIPMENT: On or about April 11, May 28, and August 16, 1947, and May 4, 1948, by the Cosmos International Corp., from New York, N. Y.

PRODUCT: 27 cartons, each containing 5 5-cc. ampuls, and 13 cartons, each containing 5 10-cc. ampuls, of *Congo red solution* at West Roxbury and Boston, Mass. Analysis showed that the product contained not more than 0.7 percent of Congo red and that it was contaminated with undissolved material.

LABEL, IN PART: "Congo-Red (Cosmos) Isotonic Sterile Solution of Congo Red For Intravenous Injection Congo Red 1.2%."

NATURE OF CHARGE: Adulteration, Section 501 (c), the strength of the article differed from that which it was represented to possess, namely, 1.2 percent Congo red, since it contained less than the declared amount of Congo red, and its purity and quality fell below that which it purported and was represented to possess since it was represented to be for intravenous use and was contaminated with undissolved material, whereas an article for intravenous use should be substantially free of undissolved material.

Misbranding, Section 502 (a), the label statement "Congo Red 1.2%" was false and misleading as applied to a product containing less than the declared amount of Congo red; and its labeling was misleading since it failed to reveal the material fact, in the light of the representation that the product was for intravenous injection, that injections for intravenous use should not be used when they are contaminated with undissolved material.

DISPOSITION: November 15, 1948. Default decrees of condemnation and destruction.

2621. Adulteration and misbranding of Congo red solution. U. S. v. 11 Boxes * * *. (F. D. C. No. 25782. Sample No. 10220–K.)

LIBEL FILED: September 27, 1948, Eastern District of New York.

ALLEGED SHIPMENT: On or about April 14, 1948, by the Drug Products Co. Inc., from Passaic, N. J.

PRODUCT: 11 boxes, each containing 25 ampuls, of *Congo red solution* at Long Island City, N. Y. Analysis showed that the product contained not more than 0.83 percent of Congo red.

NATURE OF CHARGE: Adulteration, Section 501 (c), the strength of the article differed from that which it was represented to possess, namely, 1 percent Congo red.

Misbranding, Section 502 (a), the label statement "Congo Red Solution 1% (W/V)" was false and misleading as applied to a product which contained less than the declared amount of Congo red.

DISPOSITION: November 10, 1948. Default decree of condemnation and destruction.

2622. Misbranding of Congo red solution. U. S. v. 37 Boxes * * *. (F. D. C. No. 25974. Sample No. 10798–K.)

LIBEL FILED: October 28, 1948, Eastern District of New York.

ALLEGED SHIPMENT: On or about September 20, 1948, by the Drug Products Co., Inc., from Passaic, N. J.

PRODUCT: 37 boxes, each containing 25 10-cc. ampuls, of *Congo red solution* at Long Island City, N. Y. Analysis showed that the product contained not more than 0.8 percent of Congo red.

NATURE OF CHARGE: Adulteration, Section 501 (c), the strength of the article differed from that which it was represented to possess, namely 1 percent Congo red, since it contained less than the declared amount of Congo red.

Misbranding, Section 502 (a), the label statement "Congo Red 1% (W/V)" was false and misleading.

DISPOSITION: February 2, 1949. Default decree of condemnation and destruction.

2623. Adulteration and misbranding of Estronat. U. S. v. 55 Vials * * *. (F. D. C. No. 25816. Sample No. 27396–K.)

LIBEL FILED: October 11, 1948, Eastern District of Missouri.

ALLEGED SHIPMENT: On or about June 1 and October 31, 1946, by the National Drug Co., from Philadelphia, Pa.

PRODUCT: 55 25-cc. vials of *Estronat* at St. Louis, Mo.

LABEL, IN PART: "25 cc * * * Estronat—10,000 Natural Estrogenic Hormone Substance 'National'."

NATURE OF CHARGE: The article was adulterated while held for sale after shipment in interstate commerce under Section 501 (c), in that its strength differed from that which it was represented to possess, namely, 10,000 International Units of estrone per cubic centimeter, due to estrogens from pregnant mares' urine; and, further, it was misbranded while so held for sale under Section 502 (a), in that the label statements "Estronat—10,000 * * * 10,000 International Units of Natural Estrogenic Hormone Substance * * * in each cc" were false and misleading as applied to the article, the potency of which, due to its content of estrogens as they occur in, and are extracted from, the urine of pregnant mares, was not in excess of 6,000 International Units.

DISPOSITION: November 12, 1948. Default decree of condemnation and destruction.

2624. Adulteration and misbranding of Pyo-Pheno-Chon. U. S. v. 3 Cases, etc. (F. D. C. No. 25819. Sample No. 11341–K.)

LIBEL FILED: October 15, 1948, Southern District of New York.

ALLEGED SHIPMENT: On or about April 7, 1948, by Pyo-Gon Laboratories, from Los Angeles, Calif.

PRODUCT: 3 cases, each containing 36 4-ounce bottles, of *Pyo-Pheno-Chon* at New York, N. Y., together with two leaflets entitled "Pyo-Pheno-Chon For Dental Use" and a mimeographed letter entitled "Uses of Pyo-Pheno-Chon." Chemical analysis of the product showed that it contained small proportions of a phenolic substance and an iodide, a gum, and approximately 99 percent water.

NATURE OF CHARGE: Adulteration, Section 501 (c), the strength of the article differed from that which it purported and was represented to possess, in that it was represented to be germicidal and to possess a phenol coefficient of 110, whereas the article was not germicidal and did not have a phenol coefficient of 110 against *Staphylococcus aureus* (i. e., it was not 110 times as powerful a germicide as phenol).

Misbranding, Section 502 (a), the labeling of the article contained statements which were false and misleading. The statements represented and suggested that the article was germicidal, that it possessed a phenol coefficient of 110, and that it would be effective in the treatment of trench mouth, gingivitis, pyorrhea, inflammation of the gums, pain accompanying gum-line recession, Vincent's infection, sepsis, soreness and bleeding of the gums, soreness under or around a partial or full denture, and inflammation of the mouth and throat, including third molar flaps. The article was not germicidal; it did not possess a phenol coefficient of 110; and it would not be effective in the treatment of the above-mentioned diseases and conditions.

DISPOSITION: January 19, 1949. Default decree of condemnation. It was ordered that the Food and Drug Administration be permitted to withdraw a portion of the product for its use, and that the remainder of the product be destroyed.

2625. Adulteration and misbranding of tincture of green soap. U. S. v. 76 Cases * * *. (F. D. C. No. 25915. Sample No. 23893–K.)

LIBEL FILED: November 10, 1948, Middle District of Alabama.

ALLEGED SHIPMENT: On or about July 8, 1948, by Bri-Test, Inc., from New York, N. Y.

PRODUCT: 76 cases, each containing 24 1-pint bottles, of *tincture of green soap* at Montgomery, Ala. Analysis showed that the product contained 30 percent isopropyl alcohol.

LABEL, IN PART: "Bri-Test U. S. P. Tincture of Green Soap (Soft Soap Liniment)."

NATURE OF CHARGE: Adulteration, Section 501 (d) (2), an article containing isopropyl alcohol had been substituted in whole or in part for "U. S. P. Tincture of Green Soap," which the article purported to be and which contained ethyl alcohol.

Misbranding, Section 502 (a), the name "U. S. P. Tincture of Green Soap (Soft Soap Liniment)" was false and misleading as applied to an article that was not "U. S. P. Tincture of Green Soap."

DISPOSITION: February 4, 1949. Default decree of condemnation. The product was ordered delivered to a Federal prison, for use as liquid soap.

2626. Adulteration and misbranding of tincture of green soap. U. S. v. 15 Cartons * * *. (F. D. C. No. 25680. Sample No. 31776–K.)

LIBEL FILED: September 30, 1948, Southern District of California.

ALLEGED SHIPMENT: On or about July 13, 1948, by Bri-Test, Inc., from New York, N. Y.

PRODUCT: 15 cartons, each containing 24 1-pint bottles, of *tincture of green soap* at Wilmington, Calif. Analysis showed that the product contained 28 percent isopropyl alcohol.

LABEL, IN PART: "Bri-Test U. S. P. Tincture of Green Soap (Soft Soap Liniment)."

NATURE OF CHARGE: Adulteration, Section 501 (d) (2), an article containing isopropyl alcohol had been substituted in whole or in part for "U. S. P. Tincture of Green Soap," which contains ethyl alcohol.

Misbranding, Section 502 (a), the name "U. S. P. Tincture of Green Soap (Soft Soap Liniment)" was false and misleading as applied to an article that was not "U. S. P. Tincture of Green Soap."

DISPOSITION: October 28, 1948. Default decree of condemnation and destruction.

2627. Adulteration and misbranding of tincture of green soap. U. S. v. 219 Cases * * *. (F. D. C. No. 25855. Sample No. 8348–K.)

LIBEL FILED: On or about October 28, 1948, District of New Jersey.

ALLEGED SHIPMENT: On or about July 14, 1948, by Bri-Test, Inc., from Bronx, N. Y.

PRODUCT: 219 cases, each containing 24 1-pint bottles, of *tincture of green soap* at Somerville, N. J. Analysis showed that the product contained 31 percent isopropyl alcohol and was artificially colored with D&C Yellow No. 7.

NATURE OF CHARGE: Adulteration, Section 501 (d) (2), an article containing isopropyl alcohol and artificial color had been substituted in whole or in part for "U. S. P. Tincture of Green Soap," which the article purported to be and which contained ethyl alcohol and did not contain artificial color.

Misbranding, Section 502 (a), the name "U. S. P. Tincture of Green Soap (Soft Soap Liniment)" was false and misleading as applied to an article that was not "U. S. P. Tincture of Green Soap."

DISPOSITION: December 8, 1948. Default decree of condemnation and destruction.

2628. Adulteration of prophylactics. U. S. v. 46 Gross * * *. (F. D. C. No. 25403. Sample No. 2912–K.)

LIBEL FILED: August 20, 1948, Western District of Virginia.

ALLEGED SHIPMENT: On or about July 22, 1948, by the World Merchandise Exchange & Trading Co., Inc., from New York, N. Y.

PRODUCT: 46 gross of *prophylactics* at Roanoke, Va. Examination of samples showed that 3.8 percent were defective in that they contained holes.

LABEL, IN PART: "Silver-Tex Prophylactics Manufactured by The Killian Mfg. Company, Akron, Ohio."

NATURE OF CHARGE: Adulteration, Section 501 (c), the quality of the article fell below that which it purported and was represented to possess.

Misbranding, Section 502 (a), the label statement "Prophylactics" was false and misleading as applied to an article containing holes.

DISPOSITION: January 5, 1949. Default decree of condemnation and destruction.

2629. Adulteration and misbranding of prophylactics. U. S. v. 3,600 Gross * * *. (F. D. C. No. 25275. Sample No. 23404–K.)

LIBEL FILED: August 13, 1948, Southern District of Texas.

ALLEGED SHIPMENT: On or about March 18, 1948, by the Killashun Sales Division, Inc., from Akron, Ohio.

PRODUCT: 3,600 gross of *prophylactics* at Houston, Tex. Examination of samples showed that 9.6 percent were defective in that they contained holes.

LABEL, IN PART: "Xcello's Prophylactics Mfd. by The Killian Mfg. Company, Akron, Ohio."

NATURE OF CHARGE: Adulteration, Section 501 (c), the quality of the article fell below that which it purported and was represented to possess.

Misbranding, Section 502 (a), the label statement "Prophylactics" was false and misleading as applied to an article containing holes.

DISPOSITION: February 8, 1949. Default decree of condemnation and destruction.

2630. Adulteration and misbranding of prophylactics. U. S. v. 72 Gross * * *. (F. D. C. No. 25707. Sample No. 45629–K.)

LIBEL FILED: October 13, 1948, Eastern District of Missouri.

ALLEGED SHIPMENT: On or about September 22, 1948, by the Killashun Sales Division, from Akron, Ohio.

PRODUCT: 72 gross of *prophylactics* at St. Louis, Mo. Examination of samples showed that 3 percent were defective in that they contained holes.

LABEL, IN PART: "Texide Manufactured By L. E. Shunk Latex Prod., Inc., Akron, Ohio."

NATURE OF CHARGE: Adulteration, Section 501 (c), the quality of the article fell below that which it purported or was represented to possess.

Misbranding, Section 502 (a), the label statements "Prophylactic," "Prophylactic * * * Tested * * * For Your Protection," and "Prophylatics * * * Tested * * * For Your Protection" were false and misleading as applied to an article containing holes.

DISPOSITION: November 12, 1948. Default decree of condemnation and destruction.

2631. Adulteration and misbranding of prophylactics. U. S. v. 270 Gross * * *. (F. D. C. No. 26075. Sample No. 3485–K.)

LIBEL FILED: November 17, 1948, District of Maryland.

ALLEGED SHIPMENT: On or about September 7 and 27, 1948, by the Allied Latex Corp., from Newark and Harrison, N. J.

PRODUCT: 270 gross of *prophylactics* at Baltimore, Md. Examination of samples showed that 2.99 percent were defective in that they contained holes.

LABEL, IN PART: "Blue Ribbon Sold For Prevention of Disease Only."

NATURE OF CHARGE: Adulteration, Section 501 (c), the quality of the article fell below that which it purported and was represented to possess.

Misbranding, Section 502 (a), the label statement "For Prevention of Disease" was false and misleading as applied to an article containing holes.

DISPOSITION: December 21, 1948. Default decree of condemnation and destruction.

2632. Adulteration and misbranding of prophylactics. U. S. v. 25 Gross * * *. (F. D. C. No. 25697. Sample No. 20546–K.)

LIBEL FILED: October 11, 1948, Southern District of Iowa.

ALLEGED SHIPMENT: On or about August 17, 1948, by the Dean Rubber Mfg. Co., from North Kansas City, Mo.

PRODUCT: 25 gross of *prophylactics* at Council Bluffs, Iowa. Examination of samples showed that 3.33 percent were defective in that they contained holes.

LABEL, IN PART: "Dean's Peacocks Reservoir Ends."

NATURE OF CHARGE: Adulteration, Section 501 (c), the quality of the article fell below that which it purported and was represented to possess.

Misbranding, Section 502 (a), the following statements in the labeling of the article were false and misleading as applied to an article containing holes: "Protect Your Health * * * give him complete protection * * * Peacocks are manufactured and carefully tested on the most modern up-to-date equipment known to the industry—carrying a guarantee backed by a company who for twenty years has safeguarded its customers' health through constant vigilance over its products" and "tested * * * for your protection * * * An aid in preventing venereal diseases."

DISPOSITION: December 16, 1948. Default decree of condemnation and destruction.

2633. Adulteration and misbranding of prophylactics. U. S. v. 20 Gross * * *. (F. D. C. No. 25670. Sample No. 28596–K.)

LIBEL FILED: October 12, 1948, District of Colorado.

ALLEGED SHIPMENT: On or about September 1, 1948, by the Dean Rubber Mfg. Co., from North Kansas City, Mo.

PRODUCT: 20 gross of *prophylactics* at Denver, Colo. Examination of samples showed that 2.3 percent were defective in that they contained holes. Circulars entitled "Protect Your Health" were inclosed with the product.

LABEL, IN PART: "Dean's Peacocks Reservoir Ends."

NATURE OF CHARGE: Adulteration, Section 501 (c), the quality of the article fell below that which it purported or was represented to possess.

Misbranding, Section 502 (a), the following statements were false and misleading as applied to an article containing holes: (Circular) "Protect your health When a customer purchases a prophylactic, he certainly is buying what he thinks will give him complete protection—and rightly so. It seems to us the best guide for a customer to follow to protect his confidence is to purchase a well known tried and proven brand. Peacocks are manufactured and carefully tested on the most modern up-to-date equipment known to the industry—carrying a guarantee backed by a company who for twenty years has safeguarded its customers' health through constant vigilance over its products—popularizing the Reservoir End Peacock—a great Health feature. Demand the original Peacock Reservoir End Prophylactic from your druggist" and (3-unit tin) " * * * for your protection * * * An aid in preventing venereal disease."

DISPOSITION: November 23, 1948. Default decree of condemnation and destruction.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF FALSE AND MISLEADING CLAIMS

DRUGS FOR HUMAN USE*

2634. Misbranding of Estromone. U. S. v. 42 Vials * * * (and 1 other seizure action). (F. D. C. Nos. 16027, 16378. Sample Nos. 16233–H, 31429–H, 31442–H, 31443–H.)

LIBELS FILED: May 23 and June 16, 1945, Northern District of Illinois and Southern District of California.

ALLEGED SHIPMENT: Between the approximate dates of January 1 and May 10, 1945, by Endo Products, Inc., from Richmond Hill, N. Y.

PRODUCT: *Estromone.* 42 vials at Chicago, Ill., and 128 vials at Los Angeles, Calif. The product was contained in 10-cc. and 25-cc. vials. Examination showed that it was an oil solution containing estrogenic substances consisting essentially of estradiol, with an insignificant amount, if any, of estrone.

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements in the labeling of the article "Estrogenic Substance Derived from Equine Urine," "Estrogenic Substance derived from pregnant mares' and stallions' urine," and "from natural sources" were false and misleading since the estrogenic material present in the article did not consist of estrogenic substances as derived from pregnant mares' and stallions' urine or from equine urine.

Further misbranding, Section 502 (e) (2), the article in the California lot was fabricated from two or more ingredients, and its label failed to bear the common or usual name of each active ingredient since the designation "Estrogens" appearing on some of the packages is not the specific name of any particular substance but is a generic name for a class of substances; and the statement "Estrogenic Substance derived from pregnant mares' and stallions' urine," or "Estrogenic Substance Derived from Equine Urine," appearing on the remainder of the packages, is not the common or usual name of the active ingredients of the article.

DISPOSITION: Endo Products, Inc., appeared as claimant, and in accordance with its request, the cases were consolidated and transferred to the Southern District of New York. On October 19, 1948, the claimant having admitted the allegations of the libels, judgment of condemnation was entered and the product was ordered released under bond for relabeling, under the supervision of the Federal Security Agency.

2635. Misbranding of Dr. E. L. Welbourn's Elixir. U. S. v. 77 Cartons * * *. (F. D. C. No. 24930. Sample No. 19440–K.)

LIBEL FILED: July 6, 1948, Southern District of Ohio.

ALLEGED SHIPMENT: On or about August 29, 1947, and February 10, 1948, by Dr. E. L. Welbourn Medicine Co., from Union City, Ind.

PRODUCT: 39 6-ounce cartons and 38 smaller cartons, some containing a circular entitled "Dr. E. L. Welbourn's Elixir" and each containing 1 bottle of *Dr. E. L. Welbourn's Elixir*, at Dayton, Ohio. Examination showed that the product consisted essentially of water, alcohol, potassium bicarbonate, extracts of plant drugs including a laxative plant drug, sugar, and flavoring materials.

*See also Nos. 2601, 2602, 2604–2606, 2620–2633, 2646.

NATURE OF CHARGE: Misbranding, Section 502 (a), the following statements in the circular were false and misleading since they represented and suggested that the article was effective in the treatment of the diseases, symptoms, and conditions stated and implied, whereas the article was not effective for such purposes: "Quickly relieves the disturbing distress of Belly-Ache caused by upset stomach—colic—overindulgence—nervous indigestion * * * This medicine gives prompt and speedy relief for 'Belly-Ache' caused by over-eating—nervous indigestion—gas on the stomach—upset stomach—colic. Dr. E. L. Welbourn's Elixir gives speedy relief and checks minor stomach and bowel complaints, such as vomiting and diarrhoea and is especially useful in relieving the distress caused by eating foods and liquids that upset the digestion. Very effective in relieving distress of summer complaint and intestinal flu. Also—it speedily relieves colic and upset stomachs of children. Children of all ages frequently suffer from upset stomachs. Give them this Elixir and relieve this distress. It is also an invaluable aid in relieving the distress in children caused by summer complaint and teething. This Elixir also aids in improving the digestion * * *. It is also used as a tonic and as an aid in improving the digestive processes of elderly people—also acts quickly to relieve various digestive upsets peculiar to elderly people. * * * fast acting 'Belly-Ache' reliever * * * for that sudden upset stomach or 'Belly-Ache' * * * Children cry for more * * * For simple diarrhoea, Looseness of the bowels—Pain or Griping * * * For indigestion * * * will start digestion * * * For colic * * * For upset stomach caused by teething * * * rub the Elixir on the gums to ease the discomfort."

DISPOSITION: September 10, 1948. Default decree of condemnation and destruction.

2636. Misbranding of iron and yeast tablets, and Brother Tom's Medicine. U. S. v. 54 Dozen Envelopes, etc. (F. D. C. Nos. 25461, 25462. Sample Nos. 28400–K, 29231–K.)

LIBEL FILED: August 27, 1948, District of Colorado.

ALLEGED SHIPMENT: On or about March 20, 21, 29, and 30, May 11, and June 28, 1948, by the Brother Tom's Medicine Co., from Los Angeles, Calif.

PRODUCT: 54 dozen envelopes of *iron and yeast tablets* and 54 dozen 12-ounce bottles of *Brother Tom's Medicine* at Denver, Colo. Each bottle of the medicine had one envelope of tablets attached to it by transparent adhesive tape. In addition to the tablets, each envelope contained a circular entitled "Marginal Anemia The 24 Hour Thief."

LABEL, IN PART: (Tablets) "Four Tablets Contain Iron 75 Mg. (Ferrous Sulf. Exsic. 3.9 Gr.) Yeast 12 Gr. (Primary Dried U. S. P.) B_1 (Thiamin) 1.8 mg. with excipients and fillers."

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements in the circular were false and misleading. These statements suggested and implied that the tablets would preserve a lady's beauty and prevent her face from growing pale when her freshness was lagging and her energy was low; that they would remedy puny, weak, red blood cells, enabling them to send full energy into one's system; that they would build energy, would correct tired, listless, pale conditions, and would cause the red cells to release energy to the body; and that they would favorably affect puny, faded cells, enabling them to release needed energy and cause one to look and feel one's best. The tablets would not be effective for such purposes..

DISPOSITION: October 15, 1948. No claimant having appeared, and the court having found that the tablets were misbranded as alleged in the libel and that the medicine was not misbranded under Section 502 (a), judgment was entered ordering the condemnation and destruction of the tablets. It was ordered also that the envelopes be detached from the bottles and that the medicine in the bottles be condemned and sold at public or private sale to the highest bidder. On December 23, 1948, it having appeared to the court that the medicine was misbranded because of the failure of the labeling to bear adequate directions for use for which it was intended, an amended decree was entered ordering that the medicine be destroyed.

2637. Misbranding of Red Cell Caps. U. S. v. 66 Cartons * * * (and 2 other seizure actions). (F. D. C. Nos. 25383 to 25385, incl. Sample Nos. 19487–K, 19490–K, 19491–K.)

LIBELS FILED: August 25, 1948, Western District of Kentucky.

ALLEGED SHIPMENT: On or about January 24 and 26, March 29, and July 6, 1948, by Burner Laboratories, Inc., from Evanston, Ill.

PRODUCT: 1,545 cartons each containing 1 42-capsule bottle of *Red Cell Caps* and a circular entitled "The Story of Red Cell Caps" at Louisville, Ky. Analysis indicated that the product consisted essentially of spray-dried blood, with a total iron content of 2.1 milligrams per capsule.

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements in the labeling of the article were false and misleading since the article would not be effective for the purposes suggested and implied. The statements represented and suggested that the article would be effective as a blood building food and as a supplement to the diet; that it would maintain or produce beauty, health, and vibrant energy; and that it would be efficacious in regenerating the blood.

DISPOSITION: December 1, 1948. Default decrees of condemnation and destruction.

2638. Misbranding of O. P. Analgesic Capsules. U. S. v. 14 Dozen Boxes * * *. (F. D. C. No. 26000. Sample No. 25989–K.)

LIBEL FILED: November 9, 1948, District of Minnesota.

ALLEGED SHIPMENT: On or about September 17, 1948, by Weeks & Leo Co., Inc., from Des Moines, Iowa.

PRODUCT: 14 dozen boxes of *O. P. Analgesic Capsules* at Hopkins, Minn.

LABEL, IN PART: (Boxes) "O-P Analgesic Capsules * * * Each capsule contains: Phenacetine 2 grs., Aspirin, Caffeine, Tr. Gelsemium * * * Contents Twenty Capsules."

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements on the labels of the article were false and misleading since they represented and suggested that the article was effective to relieve all the discomforts of the common cold and was effective in the relief of grippe. The article was not effective for such purposes.

DISPOSITION: March 2, 1949. Default decree of destruction.

2639. Misbranding of Cravex. U. S. v. 28 Cartons * * *. (F. D. C. No. 25662. Sample No. 23762–K.)

LIBEL FILED: On or about October 1, 1948, Eastern District of Texas.

ALLEGED SHIPMENT: On or about May 5, 1948, by Plant Products Co., Inc., from Burbank, Calif.

PRODUCT: 28 cartons of *Cravex* at Beaumont, Tex. Examination showed that the product consisted essentially of calcium and magnesium phosphate, glycerophosphates, caffeine, and milk sugar.

NATURE OF CHARGE: Misbranding, Section 502 (a), the following label statements were false and misleading since the article was not a treatment for the causes and effects of over-indulgence in liquor: (Carton) "Cravex" and (circular in some cartons) "It has been shown that alcohol chiefly affects the nervous system, which causes nervous irritability and frequently results in malnutrition. Cravex is a nerve tonic which contains several substances which are helpful in the treatment of both the causes and effects of over-indulgence."

DISPOSITION: November 8, 1948. Default decree of condemnation and destruction.

2640. Misbranding of Mentos. U. S. v. Mentos Products Co., Inc., and James Mento. Pleas of nolo contendere. Fine of $100 against each defendant. (F. D. C. No. 25570. Sample No. 10498–K.)

INFORMATION FILED: September 9, 1948, Eastern District of Pennsylvania, against Mentos Products Co., Inc., Philadelphia, Pa., and James Mento, president.

ALLEGED SHIPMENT: On or about January 14, 1948, from the State of Pennsylvania into the State of New York.

PRODUCT: Analysis showed that the product consisted essentially of an aqueous suspension of sulfur containing approximately 2.5 grams of sulfur per 100 cc., with dissolved boric acid and borates as boric acid, approximately 1.2 grams per 100 cc., and a small amount of dissolved ammonium carbonate.

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements in the labeling of the article, which included a circular entitled "Mentos Medicine," were false and misleading. The statements represented and suggested that the article would be efficacious for relief from scalp and skin diseases; that it would be effective against all types of germs; that it would relieve inflammation of the glands and acne; that it would be efficacious in the cure, mitigation, and treatment of severe cases of dandruff, eczema, psoriasis, ringworm, excess falling hair, thin dry hair, and acne. The article would not be efficacious for such purposes.

DISPOSITION: December 20, 1948. Pleas of nolo contendere having been entered, the court imposed a fine of $100 against each defendant.

2641. Misbranding of Scalpex. U. S. v. 34 Large Bottles, etc. (F. D. C. No. 24878. Sample No. 18500–K.)

LIBEL FILED: June 11, 1948, Southern District of Indiana.

ALLEGED SHIPMENT: On or about January 17, 1948, by the United Barbers Mfg. & Supply Co., from Commercial Point, Ohio.

PRODUCT: 34 large bottles and 34 small bottles of *Scalpex* at Richmond, Ind. Examination showed that the product consisted essentially of water, alcohol, soap, menthol, capsicum, perfume, and a red coloring matter.

NATURE OF CHARGE: Misbranding, Section 502 (a), the following label statements were false and misleading since the article was not effective in the

treatment of the conditions stated: "A scientific treatment for dandruff in any form, eczema, itching and other scalp troubles. Scalpex stimulates and invigorates the nerves of scalp, increasing the blood supply which nourishes the hair roots, thus aiding growth of hair. You feel it work. * * * Scalpex relieves ordinary cases of Dandruff, Itching scalp, etc., when thoroughly massaged in after the shampoo, and then used one to three times a week. In stubborn cases quick relief comes from the following treatment: 1st, apply Scalpex a little at a time; rub in well until scalp is covered. 2nd, shampoo with mild soap, using fairly hot water; 3rd, when hair is almost dry, apply Scalpex again, and dress hair. * * * After scalp is in normal condition, Scalpex will keep it healthy."

Further misbranding, Section 502 (b) (2), the article failed to bear a label containing an accurate statement of the quantity of the contents; and, Section 502 (e) (2), the label of the article failed to bear the common or usual name of each active ingredient, including the quantity, kind, and proportion of alcohol contained therein.

DISPOSITION: September 24, 1948. Default decree of forfeiture and destruction.

2642. Misbranding of A–1 Salve. U. S. v. 26 Jars, etc. (F. D. C. No. 25561. Sample Nos. 31622–K to 31624–K, incl.)

LIBEL FILED: September 8, 1948, Southern District of California.

ALLEGED SHIPMENT: On or about July 17, 1948, from Chicago, Ill.

PRODUCT: 26 4-ounce jars of *A–1 Salve regular*, 16 2-ounce jars of *A–1 Salve for minor skin irritations*, and 4 2-ounce jars of *A–1 Salve No. 2* at Los Angeles, Calif. There were also in the possession of the dealer at Los Angeles a number of placards entitled "Skin Disorders of Mycotic Infections." Two of the placards, together with dummy packages of the products, were exhibited in the dealer's window. Examination showed that the product in the 26-jar and 16-jar lots was an ointment containing sulfur, salicylic acid, and zinc oxide, and that the article in the 4-jar lot was an ointment containing tannic acid and ichthammol.

NATURE OF CHARGE: The articles were misbranded while held for sale after shipment in interstate commerce under Section 502 (a), in that the following statements and designs on the placards were misleading: "Skin Disorders * * * Varicose Ulcer * * * Weeping Eczema * * * Psoriasis * * * Alopecia Eczema * * * Try A–1 Salve [photographs showing these skin disorders]." The statements and designs represented and suggested that the articles were effective in the treatment of the diseases and conditions stated. The articles were not effective for such purposes, and the misleading impression was not corrected by the following statements which were printed in small, relatively inconspicuous type, for it was obvious that the purpose in presenting the pictures was to induce people to use the salve for such conditions: "These are photographs of limbs afflicted with Varicose Ulcers and Weeping Eczema. Such cases are due to systemic causes which require the attention of a physician. If an ointment is indicated as a dressing by the attending physician, we suggest the use of A–1 Salve No. 2," and "These are pictures of acute Psoriasis, Alopecia, and Eczema. They may become chronic and require the services of a competent physician. In such cases, if the physician advises the use of an ointment as a dressing, we suggest the use of A–1 Salve."

DISPOSITION: October 19, 1948. Default decree of condemnation and destruction.

2643. Misbranding of Algaederm Ointment and Algaederm Solution. U. S. v. 42 Cartons, etc. (F. D. C. No. 24758. Sample Nos. 25182–K to 25185–K, incl.)

LIBEL FILED: May 4, 1948, District of Minnesota.

ALLEGED SHIPMENT: On or about November 17, 1947, by the Wilson Storage & Transfer Co., from Sioux Falls, S. Dak., and by Algaederm, Inc., from Bellingham, Wash.

PRODUCT: 42 cartons, each containing 36 2-ounce jars, of *Algaederm Ointment* and 57 cartons, each containing 24 4-ounce bottles, of *Algaederm Solution* at Hopkins, Minn. Each carton contained a copy of a circular entitled "Algaederm." A circular entitled "What is Algaederm?" also accompanied the articles. Examination showed that the ointment consisted essentially of kelp extractives, soap, water, and petrolatum, and that the solution consisted essentially of kelp extractives, soap, water, and a small amount of an oil.

NATURE OF CHARGE: Misbranding, Section 502 (a), the following statements in the labeling of the articles were false and misleading since the articles were not effective in the treatment of the conditions, diseases, and symptoms stated and implied: "Uses for which Algaederm has been usually effective in bringing rapid and lasting relief: Eczema, Acne, Impetigo, and similar chronic skin disorders * * * Bruises * * * 'Jungle Rot' and Fungus Infections * * * Varicose Vein Ulcers."

Further misbranding, Section 502 (a), the following statements in the labeling of the articles were misleading since they implied that the use of soap should be avoided, whereas the articles contained soap: "Use no soap in treating with Algaederm," "do not use soap," and "Use no soap in treating with Algaederm."

DISPOSITION: Algaederm, Inc., having appeared as claimant and having requested removal of the case from the District of Minnesota, an order was entered for the removal of the case to the Eastern District of Washington. On January 24, 1949, with the consent of the claimant, judgment of condemnation was entered and the products were ordered destroyed.

2644. Misbranding of Therm Massage Infra Red Heat Applicator. U. S. v. 141 Cartons, etc. (F. D. C. No. 26072. Sample No. 12199–K.)

LIBEL FILED: November 17, 1948, Eastern District of Pennsylvania.

ALLEGED SHIPMENT: On or about October 11, 1948, by Sibert & Co., Inc., from Newark, N. J.

PRODUCT: 141 cartons, each containing 1 *Therm Massage Infra Red Heat Applicator* at Philadelphia, Pa., together with 19 display posters entitled "Therm Massage." Examination showed that the device consisted of two pieces of molded bakelite, one serving as a handle and the other containing an electrically heated coil.

NATURE OF CHARGE: Misbranding, Section 502 (a), the statement in the display posters "Use for colds, stiff neck * * * rheumatic pains, pains in back" was false and misleading since the device was not effective in the treatment of such conditions.

DISPOSITION: December 13, 1948. Sibert & Co., Inc., claimant, having consented to the entry of a decree, judgment of condemnation was entered and the product was ordered released under bond for relabeling, under the supervision of the Federal Security Agency.

2645. Misbranding of Eskimo Vibrator. U. S. v. 7 Devices * * *. (F. D. C. No. 25853. Sample No. 31625–K.)

LIBEL FILED: October 15, 1948, Southern District of California.

ALLEGED SHIPMENT: On or about September 1, 1948, by the Bersted Mfg. Co., from Fostoria, Ohio.

PRODUCT: 7 *Eskimo Vibrators* at Los Angeles, Calif. Examination showed that the device was an electric vibrator, fitted with several attachments.

LABEL, IN PART: "Eskimo Two Speed Vibrator Model 750."

NATURE OF CHARGE: Misbranding, Section 502 (a), the following statements in the labeling of the device were false and misleading since the device was not effective in the treatment of the conditions and diseases stated and implied: (Carton) "Vibrate Your Way To Health And Beauty for Sore Muscles for Complexion for Headaches * * * for Rheumatism for Constipation" and (circular attached to the device) "Vibrate Your Way To Health and Beauty * * * Where increased circulation of the blood and stimulation of the nerves causes curative action, the Eskimo Vibrator will be found very helpful. Its strong vibratory action * * * penetrates very deeply into the parts under treatment * * * complexion, sore muscles * * * neuralgia, blackheads * * * Obesity, insomnia, headaches, nervousness * * * Double chin, wrinkles, sagging muscles, acute rheumatism. Complexion: A lifeless skin and sagging facial muscles may be improved by massaging two or three minutes each day. Work from chin up and from mouth toward ears, using rotary motion. Double Chin: Use sponge applicator for three minutes at a time and work upward from base of neck toward ears—uever downward * * * Headaches and Nervousness: * * * Sore Muscles: * * * Insomnia."

DISPOSITION: December 10, 1948. Default decree of condemnation and destruction.

DRUGS FOR VETERINARY USE

2646. Misbranding of Moyer's White Liniment and Moyer's Oil of Gladness. U. S. v. Moyer Brothers, William V. Moyer, and J. Lewis Moyer. Pleas of guilty. Fine of $100 on count 1 against the corporation, with imposition of sentence on the remaining 3 counts suspended; imposition of sentence on all counts against the individuals suspended. Corporation and individual defendants placed on probation for one year. (F. D. C. No. 25591. Sample Nos. 6452–K, 12361–K to 12363–K, incl.)

INFORMATION FILED: December 20, 1948, Middle District of Pennsylvania, against Moyer Brothers, a corporation, Bloomsburg, Pa., William V. Moyer, president, and J. Lewis Moyer, secretary-treasurer.

ALLEGED VIOLATION: On or about April 15 and May 5, 1948, the defendants gave guaranties to one of their customers, guarantying that certain drugs were not adulterated or misbranded within the meaning of the Federal Food, Drug, and Cosmetic Act. The guaranty of April 15 was set forth in an order received from the customer of the defendant, which provided for the giving of a guaranty by acceptance of the order. The guaranty of May 5 was set forth on the invoice issued by the defendant to the customer. On or about April 16 and May 5, 1948, the defendant delivered to the customer, quantities of *Moyer's White Liniment* and *Moyer's Oil of Gladness* which were misbranded. In addition, on or about April 3, 1948, the defendants shipped from the State

of Pennsylvania into the State of New York a quantity of *Moyer's White Liniment*, which was misbranded.

PRODUCT: Analyses showed that *Moyer's White Liniment* consisted essentially of camphor, soap, kerosene, ammonia, and water, and that *Moyer's Oil of Gladness* consisted essentially of camphor, oil cedar leaf, and linseed oil.

NATURE OF CHARGE: Moyer's White Liniment. Misbranding, Section 502 (a), certain statements on the labels of the article were false and misleading since they represented and suggested that the article would be efficacious in the treatment of pains in the chest, side, and back, frost bites, swellings, bruises, pimples, stiff joints, lameness, inflammation, caked udder, contracted cords, sweeny, curb wounds, scratches, and similar conditions suggested by the abbreviation "etc."; and, further, that the article would be efficacious in the treatment of rheumatism, neuralgia, and sprains. The article would not be efficacious for such purposes. Further misbranding, Section 502 (f) (2), the article contained the ingredients, kerosene, ammonia, and camphor; and its labeling failed to warn that its use should be discontinued if excessive irritation developed, and that the article should not be permitted to come in contact with the eyes or mucous membrane, which warnings were necessary for the protection of users of the article.

Moyer's Oil of Gladness. Misbranding, Section 502 (a), certain statements on the label of the article were false and misleading since they represented and suggested that the article would be efficacious in the treatment of sore throat, coughs, colds, croup, sprains, wounds, bruises, neuralgia, earache, frosted feet, chilblains, and whooping cough.

Both products. Further misbranding, Section 502 (e) (2), the articles were not designated solely by names recognized in an official compendium, they were fabricated from two or more ingredients, and their labels failed to bear the common or usual name of each active ingredient, in that their labels failed to bear statements of the ingredients contained in the articles.

DISPOSITION: January 17, 1949. Pleas of guilty having been entered, the court imposed a fine of $100 on count 1 against the corporation and suspended the imposition of sentence on the remaining 3 counts; imposition of sentence against the individuals was suspended on all counts. Thereupon, the corporation and the individuals were placed on probation for 1 year, conditioned that strict compliance with the Federal Food, Drug, and Cosmetic Act be observed.

2647. Misbranding of Special Hog Mineral with Yeast, Special Yeast Minerals Dairy Feeds, Worm-O, and Ironated Hog Liquid. U. S. v. Black Hawk Chemical Co., Inc., and William H. Murphy. Pleas of guilty. Fines, $600 against corporation and $20 against individual. (F. D. C. No. 25580. Sample Nos. 24099–K, 24100–K, 24749–K, 25501–K.)

INFORMATION FILED: January 12, 1949, Northern District of Iowa, against the Black Hawk Chemical Co., Inc., Cedar Falls, Iowa, and William H. Murphy, president.

ALLEGED SHIPMENT: On or about March 17 and April 3, 1948, from the State of Iowa into the States of Wisconsin and Minnesota.

PRODUCT: Analyses disclosed that the *Special Hog Mineral with Yeast* contained 17.75 percent calcium, 2.45 percent phosphorus, .019 percent iodine, 5.95 percent sodium chloride, and 4,000 parts per million of fluorine; that the *Special Yeast Minerals Dairy Feeds* contained 18.61 percent calcium, 2.71 percent phosphorus, .018 percent iodine, 5.95 percent sodium chloride, and

4,000 parts per million of fluorine; that the *Ironated Hog Liquid* contained .016 g/100 ml. of iron; and that the *Worm-O* contained essentially Oil of Chenopodium 0.72 percent by volume, chloroform 0.56 percent, and a small amount of aromatic oil resembling anise in castor oil. The *Special Hog Mineral with Yeast* and the *Special Yeast Minerals Dairy Feeds* were accompanied by circulars entitled "Maximum Gain By Feeding Black Hawk Special Mineral Feeds" and "Dairy Yeast A Quality Mineral."

NATURE OF CHARGE: *Special Hog Mineral with Yeast.* Misbranding, Section 502 (a), the statement "Blood Purifier" in the labeling of the article was false and misleading since the article would not be efficacious to purify the blood of hogs.

Special Yeast Minerals Dairy Feeds. Misbranding, Section 502 (a), certain statements in the labeling of the article were false and misleading. These statements represented and suggested that the article would be efficacious in animals as a diuretic, a blood tonic, a general tonic, a gland activator, alterative, and expectorant; that the article would be efficacious to prevent abortion and scours; that it would be efficacious in the treatment of intestinal disorders and in the prevention and treatment of shy breeding, anemia, and lump jaw; that it would increase the amount and duration of milk production; that it would produce better health, better calves, and better digestion of feed; and that it would tone up run-down animals. The article would not be efficacious for the purposes represented.

Ironated Hog Liquid. Misbranding, Section 502 (a), certain label statements were false and misleading. These statements represented and suggested that the article contained an amount of iron which would contribute in an important respect to the needs of hogs, and that it would be efficacious in the control of hog scours, in the treatment of run-down hogs, and as a tonic for slow growing, unthrifty pigs. The article contained an insignificant amount of iron and would not be efficacious for the purposes represented. Further misbranding, Section 502 (b) (2), the label of the article bore no statement of the quantity of the contents.

Worm-O. Misbranding, Section 502 (a), the label statement "Worm-O To aid the control of Round Worms in Hogs" was false and misleading since the article would not be efficacious to aid in the control of round worms in hogs; and, Section 502 (b) (2), the label of the article bore no statement of the quantity of the contents. Further misbranding, Section 502 (e) (2), the article was not designated solely by a name recognized in an official compendium, it was fabricated from two or more ingredients, and its label failed to bear the common or usual name of each active ingredient since it contained chloroform as an active ingredient; and the label did not bear a statement of the quantity or proportion of chloroform contained therein.

DISPOSITION: January 12, 1949. Pleas of guilty having been entered, the court imposed a fine of $600 and costs against the corporation and a fine of $20 against the individual.

2648. Adulteration and misbranding of Annel Hog-Liquid. U. S. v. 58 Cans, etc. (F. D. C. No. 25776. Sample No. 25525–K.)

LIBEL FILED: September 25, 1948, District of Minnesota.

ALLEGED SHIPMENT: On or about July 12, 1948, from Omaha, Nebr., by the Anderson Feed Co.

PRODUCT: 58 1-gallon cans, 62 2-gallon cans, 147 3-gallon cans, and 56 5-gallon cans of *Annel Hog-Liquid* at Worthington, Minn. Analysis showed that

the product contained not less than 82 grains of arsenic per quart, equivalent to not less than 74 percent solution of potassium arsenite. A portion of the product was unlabeled.

LABEL, IN PART: "Annel Hog-Liquid Ingredients Calcium Phosphate, Beechwood Creosote, Potassium Iodide, Extract of Glycyrrhiza, Sodium Hydroxide, Copper Sulphate, Creosote U. S. P., Water 19.5%—Extract of Nux Vomica, giving one quart of medicine 0.10 Grams of strychnine. Solution of Potassium Arsenite 59.5%, (giving one quart of medicine 60 gr. of arsenic)."

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements on the label of the article were false and misleading since they represented and suggested that the article was effective in the treatment of intestinal infections and diarrhea of hogs. The article was not effective in the treatment of such conditions.

Further misbranding, Section 502 (b) (1), the unlabeled portion of the article failed to bear a label containing the name and place of business of the manufacturer, packer, and distributor; Section 502 (b) (2), the unlabeled portion of the article failed to bear a label containing an accurate statement of the quantity of the contents; and, Section 502 (e) (2), the label of the article failed to bear the common or usual name of each active ingredient, including the name and quantity or proportion of arsenic.

Adulteration, Section 501 (c), the strength of the article differed from that which it purported and was represented to possess, namely, "Ingredients * * * Solution of Potassium Arsenite 59.5%, (giving one quart of medicine 60 gr. of arsenic)."

DISPOSITION: January 6, 1949. Default decree of destruction.

2649. Misbranding of Humphreys Homeopathic Veterinary Preparation. U. S. v. 30 Bottles, etc. (F. D. C. No. 24877. Sample Nos. 12044–K to 12049–K, incl.)

LIBEL FILED: June 10, 1948, Middle District of Pennsylvania.

ALLEGED SHIPMENT: On or about March 26 and April 21, 1948, by the Humphrey's Medicine Co., from New York, N. Y.

PRODUCT: 30 bottles of *Humphreys Homeopathic Veterinary Preparation A.A.*, 30 bottles of *Humphreys Homeopathic Veterinary Preparation C.C.*, 15 bottles of *Humphreys Homeopathic Veterinary Preparation E.E.*, 18 bottles of *Humphreys Homeopathic Veterinary Preparation F.F.*, 20 bottles of *Humphreys Homeopathic Veterinary Preparation H.H.*, and 46 bottles of *Humphreys Homeopathic Veterinary Preparation J.K.*, at Harrisburg, Pa. Each bottle contained 1¼ fluid ounces.

LABEL, IN PART: (Preparation A.A.) "Active Ingredients * * * Aconite (Aconitum Napellus .10% Hellebore (Veratrum Viride) .088% Belladonna .075% Bryonia (Bryonia Alba) .075% Ipecac (Ipecacuanba) .062% Inert Ingredients Grain Alcohol 15% Water 84.6%"; (Preparation C.C.) "Active Ingredients * * * Poke (Phytolacca Decandra) .223% Yellow Mercurous Iodide (Mercurius Iodatus Flavus) .00056% Potassium Bichromate (Kali Bichromicum) .006% Inert Ingredients Grain Alcohol 15% Water 84.7%"; (Preparation E.E.) "Active Ingredients * * * Belladonna .133% Phosphorus .002% Aresenious Iodide (Arsenicum Iodatum) .0000000133% Inert Ingredients Grain Alcohol 15% Water 84.8%"; (Preparation F.F.) "Active Ingredients * * * Bitter Apple (Colocynthis) .116% Meadow Saffron (Colchicum Autumnale) .116% Belladonna .058% Nux Vomica .048%

China Root (Dioscorea Villosa) .0058% Inert Ingredients Grain Alcohol 15% Water 84.6%"; (Preparation H.H.) "Active Ingredients * * * Honey Bee (Apis Mellifica) .0133% Spanish Fly (Cantharis) .0133% Pipsissewa (Chimaphila Umbellata) .133% Inert Ingredients Grain Alcohol 15% Water 84.8%"; (Preparation J.K.) "Active Ingredients * * * Nux Vomica .133% Black Antimony (Antimonium Crudum) .000000089% Sulphur .000177% Club Moss (Lycopodium Clavatum) .00089% Inert Ingredients Grain Alcohol 15% Water 84.8%."

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements on the labeling of the article were false and misleading. The statements represented and suggested that the *Humphreys Homeopthic Veterinary Preparation A.A.* was effective in the treatment of simple fevers in livestock; that the *Humphreys Homeopathic Veterinary Preparation C.C.* was effective in the treatment of simple nasal catarrh in livestock; that the *Humphreys Homeopathic Veterinary Preparation E.E.* was effective in the treatment of irritations of the upper respiratory tract of livestock; that the *Humphreys Homeopathic Veterinary Preparation F.F.* was effective in the treatment of flatulent colic in livestock; that the *Humphreys Homeopathic Veterinary Preparation H.H.* was effective to increase the flow of urine in livestock; and that the *Humphreys Homeopathic Veterinary Preparation J.K.* was effective as a tonic and stimulant to the appetite of livestock. The respective articles were not effective for such purposes.

DISPOSITION: September 14, 1948. Default decree of condemnation and destruction.

2650. Misbranding of Quad-Aminos "35." U. S. v. 66 Bottles * * *. (F. D. C. No. 24624. Sample No. 15910-K.)

LIBEL FILED: May 7, 1948, Northern District of Illinois.

ALLEGED SHIPMENT: On or about February 12, 1948, by the Allen-Crowl Co., from Toledo, Ohio.

PRODUCT: 66 4-ounce bottles of *Quad-Aminos "35"* at Oak Park, Ill. Examination showed that the product was a partially hydrolyzed protein material.

NATURE OF CHARGE: Misbranding, Section 502 (a), the following label statements were false and misleading: "Indications: Distemper Recovery, Worming Recovery, Anemia, Delayed Healing, Delayed Clotting, Ulcers, Sores Around Eyes and Mouth due to Nutritional Deficiency, Rheumatic Symptoms, Skin Allergies * * * Pregnancy, Diarrhea, Coats." The statements represented and suggested that the article was effective in the treatment of the conditions named, whereas it was not effective in the treatment of such conditions.

DISPOSITION: February 3, 1949. Default decree of condemnation and destruction.

INDEX TO NOTICES OF JUDGMENT D. D. N. J. NOS. 2601 TO 2650

PRODUCTS

SHIPPERS. MANUFACTURERS, AND DISTRIBUTORS

U. S. GOVERNMENT PRINTING OFFICE: 1949

FEDERAL SECURITY AGENCY

FOOD AND DRUG ADMINISTRATION

NOTICES OF JUDGMENT UNDER THE FEDERAL FOOD, DRUG, AND COSMETIC ACT

[Given pursuant to section 705 of the Food, Drug and Cosmetic Act]

2651–2670

DRUGS AND DEVICES

The cases reported herewith were instituted in the United States district courts by the United States attorneys, acting upon reports submitted by the Federal Security Agency. Published by direction of the Federal Security Administrator.

PAUL B. DUNBAR,
Commissioner of Food and Drugs.

WASHINGTON, D. C., *December 5, 1949.*

CONTENTS*

DRUGS ACTIONABLE BECAUSE OF POTENTIAL DANGER WHEN USED ACCORDING TO DIRECTIONS

2651. Misbranding of gonorrhea treatments, sulfathiazole tablets, sleeping potion, and ephedrine and amytal capsules. U. S. v. Irvin A. Feld and Israel S. Feld (Super Cut Rate Drugs), and James W. Spriggs, Joseph D. Cabaniss, and Arlington D. Anderson. Pleas of nolo contendere. Fine of $300 against Irvin A. Feld, $300 against Israel S. Feld, and $200 against each of the other defendants. Sentence of 60 days in jail also

*For presence of a habit-forming narcotic without warning statement, see Nos. 2651, 2652; omission of, or unsatisfactory, ingredients statements, Nos. 2651, 2657; failure to bear a label containing an accurate statement of the quantity of the contents, Nos. 2651, 2657, 2659; failure to bear a label containing the name and place of business of the manufacturer, packer, or distributor, No. 2651.

imposed against each defendant, to be served in event of nonpayment of fine. (F. D. C. No. 24247. Sample Nos. 42172–H to 42174–H, incl., 42176–H, 42177–H, 90312–H, 90314–H, 90316–H, 90343–H to 90345–H, incl.)

INFORMATION FILED: May 25, 1948, District of Columbia, against Irvin A. Feld and Israel S. Feld, partners, trading as Super Cut Rate Drugs, Washington, D. C., and against James W. Spriggs, manager of the drug department of the business, and Joseph D. Cabaniss and Arlington D. Anderson, pharmacists in the drug department.

ALLEGED VIOLATION: The defendants caused certain drugs to be misbranded in interstate commerce. Between the dates of November 13, 1946, and May 27, 1947, the defendants caused the sale in the District of Columbia of 3 *gonorrhea treatments* consisting of *sulfathiazole tablets*, accompanied by a bottle containing a copaiba emulsion; two *gonorrhea treatments* consisting of methylene blue compound tablets, accompanied by a bottle containing an aqueous solution of plant extractives and potassium acetate; and two *gonorrhea treatments* consisting of *oil of santal capsules*, one treatment accompanied by a copaiba emulsion and the other accompanied by an aqueous solution of plant extractives and potassium acetate.

The defendants caused also the sale in the District of Columbia of one lot of *oil of santal capsules*, one lot of *sulfathiazole tablets*, a "*sleeping potion*" consisting of a mixture of bromides and phenobarbital, and one lot of *ephedrine and amytal tablets*. Amytal contains a derivative of barbituric acid.

The drugs so caused to be sold by the defendants were misbranded because of failure to comply with the various labeling requirements of the law.

NATURE OF CHARGE: Misbranding, Section 502 (f) (1), the labeling of the products failed to bear adequate directions for use since they failed to reveal the conditions for which the drugs were intended; Section 502 (b) (1) and (2), certain of the products failed to bear a label containing a statement of the quantity of the contents and the name and place of business of the manufacturer, packer, or distributor; and, Section 502 (d), the *sleeping potion* and the *ephedrine and amytal capsules* contained a chemical derivative of barbituric acid, which has been designated as habit forming, and their labels failed to bear the name and quantity or proportion of such derivative and the statement "Warning—May be habit forming."

Further misbranding, Section 502 (e) (1) and (2), with the exception of the *ephedrine and amytal tablets*, the labels failed to bear the common or usual names of the drug, in those instances involving a single drug, and failed to bear the common or usual names of the active ingredients in those drugs that were composed of two or more ingredients; also, in the case of three of the *gonorrhea treatments*, the labels failed to bear a statement of the quantity, kind, and proportion of alcohol present; and the label of the *sleeping potion* bore no statement containing the name and quantity or proportion of the bromides contained in the article.

Further misbranding, Section 502 (j), the *sulfathiazole tablets* in one of the *gonorrhea treatments* would be dangerous to health when used as directed in the labeling, "2 after meals," and the *sleeping potion* would be dangerous to health when used as directed since such use would result in the daily consumption of bromides in an amount which would be dangerous to health; and Section 502 (a), the directions "2 after meals" on the box of one of the lots

of *sulfathiazole tablets* were misleading since they implied that the product would be safe and appropriate for administration when used as so directed, whereas it was not safe and appropriate for use but was dangerous to health when so used.

DISPOSITION: October 28, 1948. Pleas of nolo contendere having been entered, the court fined both Irvin A. Feld and Israel S. Feld $300 on each of counts 9 through 18, covering five of the *gonorrhea treatments* and the *ephedrine and amytal capsules*, and sentenced each individual to serve 60 days in jail in event of nonpayment. The fines were to run concurrently on each count. James W. Spriggs was sentenced to pay a fine of $200 on each of counts 1 through 8, covering three of the *gonorrhea treatments*, the *sulfathiazole tablets*, and the *sleeping potion*, or to serve 60 days in jail in the event of nonpayment. These fines also were to run concurrently. Joseph D. Cabaniss and Arlington D. Anderson were given the same sentence as defendant Spriggs, covering charges in the case of defendant Cabaniss as set forth in counts 1, 2, 3, 4, 7, 9, 10, 15, and 16 relating to four of the *gonorrhea treatments* and the *sulfathiazole tablets*, and covering the charges in the case of defendant Anderson as set forth in counts 5, 6, 8, 11, 12, 13, 14, 17, and 18 relating to four of the *gonorrhea treatments*, the *sleeping potion*, and the *ephedrine and amytal capsules*.

DRUGS ACTIONABLE BECAUSE OF FAILURE TO BEAR ADEQUATE DIRECTIONS OR WARNING STATEMENTS*

2652. Misbranding of phenobarbital sodium capsules, phenobarbital tablets, and nembutal capsules. U. S. v. John Altergott (John Altergott Drug Co.). Plea of not guilty. Tried to the court. Verdict of guilty. Fine, $175 and costs. (F. D. C. No. 25584. Sample Nos. 20517–K to 20520–K, incl., 20523–K, 20524–K, 20527–K.)

INFORMATION FILED: January 3, 1949, Western District of Missouri, against John Altergott, trading as the John Altergott Drug Co., Kansas City, Mo.

INTERSTATE SHIPMENT: Between the approximate dates of October 16, 1947, and June 4, 1948, from Bristol, Tenn., and North Chicago, Ill., to Kansas City, Mo., of quantities of *phenobarbital sodium capsules*, *phenobarbital tablets*, and *nembutal capsules*.

LABEL, WHEN SHIPPED: "Capsules Phenobarbital Sodium 1½ Grs. (0.1 Gm.)," "Tablets Phenobarbital 1½ GRS. (0.1 Gm.)," and "Capsules Nembutal (Pentobarbital Sodium * * *) 1½ grs."

ALLEGED VIOLATION: The products were made and labeled by the manufacturer to be dispensed only by or on the prescription of a physician. On or about June 25 and July 1, 2, 6, and 7, 1948, while the drugs were being held for sale after shipment in interstate commerce, the defendant removed portions of the drugs from the bottles in which they had been shipped, repacked them in cartons and envelopes, and sold them to various persons without a prescription, which acts of the defendant resulted in the drugs being misbranded.

NATURE OF CHARGE: Misbranding, Section 502 (d), the articles were drugs for use by man and contained chemical derivatives of barbituric acid, which derivatives had been found by the Administrator of the Federal Security Agency after investigation to be, and by regulations designated as, habit forming;

*See also No. 2651.

and the labels of the repackaged drugs failed to bear the name and quantity or proportion of such derivative and, in juxtaposition therewith, the statement "Warning—May be habit forming."

Further misbranding, Section 502 (f) (1), the cartons and envelopes into which the drugs had been repacked bore no labeling containing directions for use; and, Section 502 (f) (2), the carton and envelopes containing the drugs bore no labeling containing warnings against use in those pathological conditions where their use may be dangerous to health and against unsafe dosage and duration of administration.

DISPOSITION: A plea of not guilty having been entered, the case came on for trial before the court on March 9, 1949. At the conclusion of the testimony, the court found the defendant guilty, and on March 23, 1949, imposed a fine of $175, plus costs.

2653. Misbranding of Sanagan Agermo disinfectant. U. S. v. 4 Cans * * *. (F. D. C. No. 25852. Sample No. 10582-K.)

LIBEL FILED: October 15, 1948, Southern District of New York.

ALLEGED SHIPMENT: From Laboratories Agermo, Barcelona, Spain, arriving in New York, N. Y., on or about August 10, 1947.

PRODUCT: 4 cans, each containing 1 gallon, of *Sanagan Agermo disinfectant* at New York, N. Y. The invoice stated that the product contained copper sulfate, zinc sulfate, calcium sulfate, formol, sodium chloride, gentian extract, sodium salicylate, and water. The Alcon Export Corp., which was in possession of the product at New York, mailed to prospective purchasers a leaflet in which the product was offered to prevent and check epidemics, especially hoof-and-mouth disease. It was also offered as a safeguard and treatment of cattle against any type of contagious disease.

NATURE OF CHARGE: Misbranding, Section 502 (f) (1), the labeling of the article failed to bear adequate directions for use for the purposes for which it was intended, namely, to prevent and check epidemics, especially hoof-and-mouth disease, and as a safeguard and treatment of cattle against any type of contagious disease.

DISPOSITION: January 19, 1949. Default decree of condemnation and destruction.

DRUGS ACTIONABLE BECAUSE OF THE PRESENCE OF NONCERTIFIED COAL-TAR COLORS

2654. Adulteration and misbranding of Premo Vasodrine Solution of Epinephrine Hydrochloride and adulteration of Premo-Rub Liniment and Premo Elixir Preminal. U. S. v. Premo Pharmaceutical Laboratories, Inc., and Theodore A. Blackman. Pleas of not guilty. Tried to the court. Verdict of guilty against corporation on all 6 counts of information; verdict of guilty against individual on 5 counts of information; and verdict of not guilty against individual on count 6 relating to Premo Elixir Preminal. (F. D. C. No. 16594. Sample Nos. 78198-F, 120-H, 121-H, 22314-H.)

INFORMATION FILED: October 21, 1947, Southern District of New York, against the Premo Pharmaceutical Laboratories, Inc., New York, N. Y., and Theodore A. Blackman, president and treasurer of the corporation.

ALLEGED SHIPMENT: On or about October 23, 1944, and January 15, March 15, and April 4, 1945, from the State of New York into the States of Missouri, Pennsylvania, and Florida.

NATURE OF CHARGE: *Premo Vasodrine Solution of Epinephrine Hydrochloride.* Adulteration, Section 501 (b), the article purported to be and was represented as "Solution of Epinephrine Hydrochloride," a drug the name of which is recognized in the United States Pharmacopoeia, an official compendium, and its strength differed from and its quality fell below the official standard since the drug had a potency ranging from 27 percent to 56 percent of the potency required by the United States Pharmacopoeia; and its difference in strength and quality from the official standard was not stated on the label. Misbranding, Section 502 (a), the label statement "Solution of Epinephrine Hydrochloride U. S. P. 1–1000" was false and misleading since it represented and suggested that the article consisted of Solution of Epinephrine Hydrochloride which conformed with the requirements of the United States Pharmacopoeia, and that it possessed a potency equivalent to that possessed by a solution containing 1 gram of U. S. P. Epinephrine Reference Standard in each 1,000 cc. The article did not conform with the requirements of the Pharmacopoeia for "Solution of Epinephrine Hydrochloride," and it possessed a potency equivalent to less than that represented.

Premo-Rub Liniment. Adulteration, Section 501(a)(4), the article contained for purposes of coloring only a coal-tar color, Butter Yellow, which color had not been listed for use in drugs in accordance with the regulations and was other than one from a batch that had been certified.

Premo Elixir Preminal. Adulteration, Section 501(a)(4), the article contained for purposes of coloring only a coal-tar color, Methyl Violet, which color had not been listed for use in drugs in accordance with the regulations and was other than one from a batch that had been certified.

DISPOSITION: Pleas of not guilty having been entered, the case came on for trial before the court on March 14, 1949. At the conclusion of the trial on March 17, 1949, the corporation was found guilty on all 6 counts of the information and was fined $1,200. The individual was found guilty on 5 counts of the information and not guilty on count 6 relating to the *Premo Elixir Preminal*, and he was fined $500.

2655. Adulteration of Cornocide (corn remedy). U. S. v. Denver Pharmaceutical Mfg. Co., Inc., and Samuel Garber, David Kaplan, and Samuel Sherman. Pleas of guilty. Fines of $600 against corporation, $50 each against defendants Garber and Kaplan, and $20 against defendant Sherman. (F. D. C. No. 21471. Sample Nos. 8580–H, 8581–H.)

INFORMATION FILED: September 17, 1948, Eastern District of New York, against the Denver Pharmaceutical Mfg. Co., Inc., Long Island City, N. Y., and against Samuel Garber, president, David Kaplan, treasurer, and Samuel Sherman, secretary.

ALLEGED SHIPMENT: On or about May 23, 1946, from the State of New York into the State of New Jersey.

NATURE OF CHARGE: Adulteration, Section 501 (a) (4), the article contained, for purposes of coloring only, coal-tar colors, Butter Yellow (Colour Index No. 19) and Sudan IV (Colour Index No. 258), which had not been listed for

use in drugs in accordance with the regulations, and were other than ones from batches that had been certified in accordance with the regulations.

DISPOSITION: On December 8, 1948, pleas of guilty were entered on behalf of all defendants. On January 13, 1949, the court imposed a fine of $600 against the corporation, and January 20, 1949, the court imposed fines of $50 each against defendants Garber and Kaplan and $20 against defendant Sherman.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF DEVIATION FROM OFFICIAL OR OWN STANDARDS*

2656. Action to enjoin and restrain the interstate shipment of isotonic solution of sodium chloride, water for injection, epinephrine hydrochloride injection, aminophylline, sodium ascorbate and dextrose injection, sodium iodide and sodium salicylate, sodium iodide and sodium salicylate with colchicine, sodium cacodylate, and sodium thiosulfate. U. S. v. Bristol Laboratories, Inc. Tried to the court. Case dismissed. (Inj. No. 198.)

COMPLAINT FILED: On or about September 25, 1948, Northern District of New York, against Bristol Laboratories, Inc., Syracuse, N. Y. The complaint alleged that the defendant had been and was then shipping in interstate commerce drugs which were adulterated and misbranded.

NATURE OF CHARGE: Adulteration, Section 501 (b), the *isotonic solution of sodium chloride, water for injection, epinephrine hydrochloride injection, aminophylline, and sodium ascorbate and dextrose injection* purported to be and were represented as drugs, the names of which are recognized in the United States Pharmacopoeia, and the *sodium iodide and sodium salicylate, sodium iodide and sodium salicylate with colchicine, sodium cacodylate,* and *sodium thiosulfate* purported to be and were represented as drugs, the names of which are recognized in the National Formulary; and the purity and quality of the drugs fell below the official standards therefor since they were not and had not been substantially free of undissolved material which could be detected readily without magnification when tested in accordance with the method prescribed by the standards; and the differences of the drugs in quality and purity from the standards were not plainly stated, or stated at all, on their labels.

Misbranding, Section 502 (a), the names of the drugs, *isotonic solution of sodium chloride, water for injection, epinephrine hydrochloride injection, aminophylline, and sodium ascorbate and dextrose injection,* and the statement "U. S. P." appearing in the labeling of a number of such drugs, were false and misleading since such names and statement represented and suggested that the drugs conformed to the specifications of the United States Pharmacopoeia, whereas they did not conform to such specifications.

PRAYER OF COMPLAINT: That a preliminary injunction issue, restraining the defendant from commission of the acts complained of; and that, after due proceedings, the preliminary injunction be made permanent.

DISPOSITION: Pursuant to a motion filed on behalf of the defendant, the court on October 8, 1948, entered an order directing the Government to show cause why an order should not be made requiring it to answer the following interrogatories:

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*See also No. 2654.

1. State when said drug was introduced into interstate commerce by the defendant in violation of the Federal statute as alleged in the complaint.

2. Where did the plaintiff obtain samples of said drug and on what date and from whom?

3. Was the sample obtained by the plaintiff contained in a vial or ampule?

4. What was the size of the vial or ampule in which the drug was contained?

5. What was the lot number or numbers on the label on the vial or ampule in which said drug was contained? If the plaintiff obtained more than one sample, state the number of samples it obtained of said drug, and if they where in different vials or ampules, state the size of each of the vials and ampules and the respective lot numbers shown on the labels.

6. State in detail what was done with each sample of said drug prior to their examination.

7. State when and where such examination was made and by whom made.

8. State in detail the qualifications of the person making such examination.

9. State in detail the method employed by such person in making the examination and attach copy of any report covering said examination made by said person.

10. If more than one examination was made by the same person, or if more than one person made the examination of said drug, state the names of all persons making the examination, the qualifications of said persons, and attach reports of all examinations made by either or all of said persons covering all samples of said drug.

11. State the nature, chemical, and physical properties, size and number of the undissolved particles found in each of said samples examined by the plaintiff.

12. Describe in detail any and all devices and techniques used in the examination of said drug during the examination.

13. How were the ampules or vials of each sample of said drug treated or handled by plaintiff before examination?

14. Set forth in detail each of the steps followed in making each of said examinations.

15. State how much time was consumed in the actual examination of each of said samples of said drug.

16. How many of such examinations were made on the dates above set forth by each of the persons whose names are above set forth?

17. What other work had been performed by each of said persons on each of said dates prior to examining said drugs?

18. How long after each of said persons began work on each of said dates was said drug examined?

19. What test had been made of the vision of each of the persons above named, and when was each of said tests made and by whom? What was the result of each such test?

20. What in detail, is the interpretation which plaintiff places upon the terms "substantially free" of "undissolved material," "detected readily," "without magnification," "without excessive magnification," and "normal vision"?

21. When was said interpretation adopted? Has said interpretation been changed at any time since 1942? If so, what were the changes in said interpretation, and when were said changes made?

22. What has been the care and treatment of each of said samples of said drugs which were examined since the date of each of said examinations?

23. If a 100 watt incandescent lamp was used, what was the rated voltage at the time it was being operated?

In addition, the order of October 8 directed the Government to show cause why an order should not be made requiring it to make discovery of (1) samples of each of the lots of the allegedly adulterated drugs named in the complaint; (2) the solution and the container used in testing each of the drugs; and (3) photostatic copies of any reports made showing the results of the test and a description of the manner in which the tests were made. A motion also was filed by the defendant to have the complaint made more definite and certain. On October 26, 1948, an answer to the motion was filed giving the information requested. On the same date, answers to certain of the interrogatories, together with information on certain of the matters requested by way of discovery, were filed by the Government, accompanied by objections to answering the other interrogatories and to making discovery of certain matters. The objections and briefs and arguments of counsel were taken under advisement by the court, and on November 13, 1948, the court handed down the following opinion:

BRENNAN, *District Judge:* "Several motions have been made in this action, all of which have been disposed of by the action of the parties, except the matter of answering certain interrogatories heretofore served upon the plaintiff by the defendant. The propriety of the interrogatories comes before this Court through the medium of an order to show cause, which was returnable on October 11, 1948. This decision is directed to that question alone.

"The defendant seeks to propound some twenty-three interrogatories, the answers to which defendant claims are required in order to prepare for trial properly.

"The plaintiff has already filed answer to interrogatories Nos. 1 to 8 inclusive, 13, 22 and part of 9, so that no discussion of same is made in this memorandum.

"This is an action in which the sale or introduction of certain drugs in interstate commerce is sought to be restrained by injunction, for the reason that same, as manufactured by the defendant, fails to meet the requirements of the Federal Food, Drug and Cosmetic Act. A proceeding looking to the granting of a temporary injunction has been commenced by the plaintiff, and same is held in abeyance since it is evident that a trial upon the merits may be had without undue delay.

"The test to which the drugs might be subjected in order to ascertain whether or not they comply with the provisions of law appears on its face to be capable of conflicting constructions, and its application will apparently become a basis of dispute in this litigation.

"It is unnecessary to discuss in detail the law applicable to the dispute arising upon this motion. The defendant relies upon Rule 33 of the Federal Rules of Civil Procedure, and the provisions of Rule 26, as referred to therein. Both rules have been many times subject to judicial interpretation, and it is sufficient to say that the weight of judicial precedents is that they shall be applied with liberality to the end that the parties may not be surprised upon the trial of the action. In deciding this motion the Court has in mind such a construction and application of the rule, and it also has in mind that the plaintiff, in applying for a temporary injunction, would be required to establish affirmatively a basis for that relief which would, in effect, give to the defendant a somewhat detailed basis of the action prior to the trial thereof. It would

seem, therefore, that no serious objection should be made to the answering of any interrogatory which calls for evidence which would be required to be produced upon the temporary injunction proceeding. The cases of U. S. vs. 300 Cans, etc., 7 F. R. D. 36, and U. S. v. 88 Cases, etc., 5 F. R. D. 503, have been considered.

"A consideration of the disputed interrogatories follows:

"Interrogatory No. 9. This interrogatory has been partially answered, and the plaintiff apparently objects to the attaching of a copy of any report covering the examination made by the plaintiff of the drugs manufactured by the defendant. No valid reason exists for such objection. The report would necessarily become part of the temporary injunction proceeding. It is the basis of the action. The interrogatory is allowed.

"Interrogatory No. 10 is allowed.

"Interrogatory No. 11 is disallowed, since the reports in Interrogatories Nos. 9 and 10 will cover the substance of the interrogatory, if, in fact, a record were made of the size and number of the undissolved particles.

"Interrogatory No. 12 is allowed. The information called for may possibly be covered in the answers to Interrogatories Nos. 9 and 10.

"Interrogatory No. 14 is allowed.

"Interrogatory No. 15 is allowed.

"Interrogatories Nos. 16, 17 and 18 are disallowed. They call for details which would seem to be unnecessary at this time. Their propriety may arise on cross examination.

"Interrogatory No. 19. This interrogatory assumes that tests have been made of the vision of the persons conducting the tests. As phrased it would seem to call for unnecessary details. It would seem, however, that the defendant is entitled to know, and the plaintiff is required to show, that the persons conducting the tests possessed and used normal vision, as that term is defined in the test prescribed. The interrogatory is re-framed as follows: 'What means or precautions were taken to establish as a fact that the person or persons at the times of making the tests possessed and used normal vision in the conduct thereof?' The interrogatory as re-framed, if accepted by the defendant, is allowed. The interrogatory as propounded is disallowed.

"Interrogatory No. 20. It is apparent that the expressions in the interrogatory 'without excessive magnification' was intended to read 'without accessory magnification.' The interrogatory is allowed as to all of the terms therein, except 'Detected readily,' 'without magnification' and 'without accessory magnification.' These three terms define themselves. The other terms in the interrogatory may be the subject of dispute which might arise from a difference in interpretation between a chemist and a manufacturer. Such dispute, if it exists, should be openly defined prior to the trial of the issues. The interrogatory is allowed, with the exception of the three expressions or terms excluded as above set forth.

"Interrogatory No. 21 is allowed.

"Interrogatory No. 23 is allowed.

"Order may be submitted accordingly."

Answers to the interrogatories were subsequently filed in accordance with the foregoing opinion. An answer to the complaint was filed on behalf of the defendant, denying that the products were adulterated or misbranded and alleging that the sections of the act involved were unconstitutional and void because (1) such sections attempted to delegate legislative power to persons

who publish or might publish the United States Pharmacopoeia or the National Formulary, (2) such sections set forth no standard for the guidance of the person to whom the legislative power was delegated, (3) such sections purported to require compliance with standards adopted after the effective date of such sections and failed to set forth any requirements for notice or hearing prior to adoption of the standards or for judicial review thereof, and (4) the drug standards involved in the case were vague, uncertain, arbitrary, and capricious. In addition the defendant's answer alleged that the drug standards were illegal and void, in that enforcement of the standards would be in violation of the Administrative Procedure Act because the defendant had neither notice nor opportunity for hearing prior to adoption of the standard and no opportunity for judicial review thereafter.

The case came on for trial on January 17, 1949, and at the conclusion of the testimony for the Government on January 25, 1949, the court granted the defendant's motion for dismissal of the case on the ground (1) that the standards involved were indefinite and (2) that the evidence was insufficient to show such violation of the Act as would warrant the granting of the relief prayed for.

2657. Action to enjoin and restrain the interstate shipment of Kamba or Kamba Tonic. U. S. v. John L. Denney. Tried to the court. Injunction granted. Action for violation of injunction tried to the court. Defendant placed on 6 months' probation. (Inj. No. 98.)

COMPLAINT FILED: May 25, 1944, Southern District of California, against John L. Denney, Fresno, Calif., alleging that the defendant was engaged in the manufacture, production, and sale of a product known as *Kamba* and *Kamba Tonic;* that the product was manufactured from a herb of the rose family, probably of *Chamaebatia foliolosa*, commonly known as bear grass or mountain misery; that it was prepared in three forms, a ground dried herb, the water extract of the herb preserved with sodium benzoate, and the distilled form which is the condensate obtained when boiling the herb with water in the preparation of the water extract of the herb.

The complaint alleged further that the defendant had been and was still shipping the products in interstate commerce under labeling which represented that the herb form was an antitoxin and antiseptic for internal and external use; that it was a tonic and would cure many conditions and diseases, especially arthritis; that the liquid preparation was an antiseptic for internal and external use and was effective as a treatment for disorders of the stomach and bowels, for constipation, hemorrhoids, and arthritis; that the herb and liquid products were capable of destroying poison and bacteria and were beneficial for internal and external troubles, carbuncles, skin diseases, arthritis, bronchial, lung, ear, and eye troubles, sinus and hay fever, scalds, burns, cuts, bruises, boils, athlete's foot, dandruff, constipation, female trouble, gall bladder, stomach ulcers, sleeping sickness, mastitis in cows, dysentery and pneumonia in calves and poultry, streptococcus in chickens and turkeys, and pneumonia and paralysis in chickens; that the products contained 24,000 International Units of vitamin A and "a lot of vitamin B_1"; that they were "preventive medicine accepted by the United States through the mails as being OK"; that they were recommended for eczema, poison oak and ivy, neuralgia, arthritis, and other rheumatisms, open sores, and all forms of skin diseases; that they would clear up the average case of arthritis in about 3 months; that they would kill poisons and cleanse the system; and that "most of the demand for the herb is for arthritis though it is wonderful for stomach ailments and in fact any ailment."

NATURE OF CHARGE: Misbranding, Section 502 (a), the statements in the labeling above referred to were false and misleading; Section 502 (b) (2), the labels failed to bear a statement of the quantity of the contents; and, Section 502 (e), the labels failed to bear a statement of the common or usual names of the active ingredients.

Adulteration, Section 501 (c), the strength of the articles differed from, and their quality fell below, that which they purported and were represented to possess since they were not "antitoxin" and "antiseptic," as represented.

PRAYER OF COMPLAINT: That the defendant be restrained and enjoined from shipping in interstate commerce the drugs "Kamba" or "Kamba Tonic."

DISPOSITION: On or about August 30, 1945, a default decree was entered granting the injunction. On September 26, 1945, the defendant filed a motion to set aside the default decree, which was granted on October 8, 1945.

On December 5, 1946, a decree for a permanent injunction was entered enjoining the defendant from introducing or causing to be introduced into interstate commerce any herb concoction, distillate, or other preparations under the name of "Kamba" or "Kamba Tonic" or any preparation made from the genus of herbs known as *Chamaebatia*. On December 27, 1946, the writ of injunction in accordance with said decree was issued.

On or about April 23, 1947, a complaint was filed charging violation of the writ of injunction. On October 3, 1947, the matter having been tried before the court, the defendant was found guilty of contempt and was sentenced to 6 months' imprisonment. The sentence was suspended, and the defendant was placed on probation for 6 months.

2658. Adulteration of Dr. E. R. Eatons Formula. U. S. v. 3 Boxes * * *. (F. D. C. No. 25770. Sample No. 9075–K.)

LIBEL FILED: September 21, 1948, District of New Jersey.

ALLEGED SHIPMENT: On or about August 2, 1948, by the C. F. Kirk Co., from New York, N. Y.

PRODUCT: 3 boxes, each containing 25 ampuls, of *Dr. E. R. Eatons Formula* at Teaneck, N. J.

NATURE OF CHARGE: Adulteration, Section 501 (c), the purity and quality of the article fell below that which it purported and was represented to possess since it was represented for intravenous use and was contaminated with undissolved material, whereas an article intended for intravenous use should be substantially free of undissolved material.

DISPOSITION: March 28, 1949. Default decree of condemnation and destruction.

2659. Adulteration and misbranding of prophylactics. U. S. v. 5 Gross * * *. (F. D. C. No. 26120. Sample No. 3876–K.)

LIBEL FILED: December 7, 1948, District of Columbia.

ALLEGED SHIPMENT: On or about September 16, 1948, by the Blue Ribbon Co., from Baltimore, Md.

PRODUCT: 5 gross of *prophylactics* at Washington, D. C. The product was packed in 3-unit tins, 4 tins to the package and 12 packages to the carton. Examination of samples showed that 2.45 percent were defective in that they contained holes.

LABEL, IN PART: "Blue Ribbon De Luxe."

NATURE OF CHARGE: Adulteration, Section 501 (c), the quality of the article fell below that which it purported and was represented to possess.

Misbranding, Section 502 (a), the label statements "* * * * tested by air * * * for prevention of disease * * *" were false and misleading as applied to an article containing holes; and, Section 502 (b) (2), the article failed to bear a label containing an accurate statement of the quantity of the contents since the three-units tins and the package containing 4 tins of the article bore no statement of the quantity of the contents, and the statement on the gross-carton "One-Dozen" was inaccurate since the carton contained one gross.

DISPOSITION: April 6, 1949. Default decree of condemnation and destruction.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF FALSE AND MISLEADING CLAIMS*

DRUGS FOR HUMAN USE

2660. Misbranding of estrogenic hormones in oil. U. S. v. Barry Laboratories, Inc., and Aaron W. Barry. Pleas of nolo contendere. Fine of $1,000 against each defendant. (F. D. C. No. 25573. Sample No. 19243–K.)

INFORMATION FILED: September 30, 1948, Eastern District of Michigan, against Barry Laboratories, Inc., Detroit, Mich., and Aaron W. Barry, president of the corporation.

ALLEGED SHIPMENT: On or about October 27, 1947, from the State of Michigan into the State of Ohio.

LABEL, IN PART: "Estrongenic Hormones * * * Manufactured For The Schuemann-Jones Co. Cleveland, Ohio."

NATURE OF CHARGE: Misbranding, Section 502 (a), the label statements "Estrogenic Hormones A sterile, standardized solution of estrogenic hormones derived from gravid equine urine consisting principally of Estradiols with small quantities of Estrone, Equilin and Equilenin and traces of Alpha-Estradiol in neutral vegetable oil" and the statement "This preparation is a standardized oil solution of Estrogenic Hormones obtained from pregnancy urine," appearing in a circular enclosed with the article, were false and misleading. The statements represented and suggested that the article contained estrogens as they are found in, and abstracted from, gravid equine urine and that the article contained only traces of alpha-estradiol. The article did not consist of estrogens as they are present in, and abstracted from, gravid equine urine, and it did not contain only traces of alpha-estradiol since the predominant estrogen present in the article was alpha-estradiol.

DISPOSITION: February 28, 1949. Pleas of nolo contendere having been entered, the court imposed a fine of $1,000 against each defendant.

2661. Misbranding of Systemic Pilana Combination Tablets and Pilana Rectal Salve. U. S. v. Dr. Edward T. Molzahn (McCook Rectal Clinic). Plea of nolo contendere. Fine, $100 and costs. (F. D. C. No. 24281. Sample No. 21407–K.)

*See also Nos. 2651, 2654, 2656, 2657, 2659.

INFORMATION FILED: February 21, 1949, District of Nebraska, against Dr. Edward T. Molzahn, trading as the McCook Retcal Clinic, McCook, Nebr.

ALLEGED SHIPMENT: On or about January 10, 1948, from the State of Nebraska into the State of Missouri.

PRODUCT: Analysis showed that the *Systemic Pilana Combination Tablets* contained a minute amount of a calcium salt, an indication of podophyllum, unidentified plant material, and a large amount of talc filler; and that the *Pilana Rectal Salve* contained chiefly benzocaine, hydroxyquinoline sulfate, and unidentified plant extractives in a petrolatum base.

NATURE OF CHARGE: Misbranding, Section 502(a), certain statements in the accompanying labeling of the articles were false and misleading. These statements represented and suggested that the *Systemic Pilana Combination Tablets* would alleviate the pain and discomfort of constriction of rectal veins and arteries; that it would relieve the discomfort due to piles, hemorrhoids, and prolapsus ani; that it would relieve a congested condition; that it would strengthen the walls of the hemorrhoidal veins and tone the lower bowel; that it would be efficacious in the cure, mitigation, and treatment of systemic diseases, and would regulate the liver; and that the *Systemic Pilana Combination Tablets* and the *Pilana Rectal Salve*, when used alone and in conjunction with each other, would be efficacious in the cure, mitigation, and treatment of hemorrhoids, piles, and other rectal ailments.

DISPOSITION: March 21, 1949. A plea of nolo contendere having been entered, the court imposed a fine of $100 and costs.

2662. Misbranding of salve. U. S. v. Frank Endinger. Plea of nolo contendere. Fine, $10. (F. D. C. No. 25331. Sample Nos. 25035–K, 31741–K.)

INFORMATION FILED: November 18, 1948, District of Arizona, against Frank Endinger, Willcox, Ariz.

ALLEGED SHIPMENT: On or about July 1, 1947, and June 15, 1948, from the State of Arizona into the States of North Dakota and California.

PRODUCT: Analysis disclosed that the product was essentially lead oleate and sodium carbonate with rosin.

LABEL, IN PART: (Jar label, shipment of July 1, 1947) "Principal Ingredients No. 1 Dark Salve—Olive oil, Rosin, Oleate of Lead, Soap lake salts, Sweet oil, Croton oil. No. 2 Light Salve—Lanun anhydrous, Menthol crystals, Witch Hazel, Oil of Wintergreen, Oil of Eucalyptus, Croton oil."

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements in accompanying labeling were false and misleading. The labeling of both shipments represented and suggested that the article would be efficacious in the treatment of cancer. The labeling of the shipment of June 15, 1948, represented and suggested that the article also would be efficacious in the treatment of pneumonia, skin diseases, ulcers, catarrh, tuberculosis, rheumatism, kidney disease, eczema, ringworm, burger's disease, milk leg, female trouble, barber's itch, fistula, piles, and stomach diseases, and that the article would prevent blood poisoning and gangrene. The article would not be efficacious for the purposes represented.

DISPOSITION: January 31, 1949. A plea of nolo contendere having been entered, the court imposed a fine of $10.

2663. Misbranding of Leuco-Derm Ointment. U. S. v. 30 Cartons, etc. (F. D. C. No. 24943. Sample Nos. 43438–K, 43439–K.)

LIBEL FILED: July 20, 1948, Northern District of Illinois.

ALLEGED SHIPMENT: On or about April 26, 1948, by the Mann Chemical Co., from Detroit, Mich.

PRODUCT: 30 ½-ounce cartons, 12 1-ounce cartons, and 6 2-ounce cartons of *Leuco-Derm Ointment Regular* and 6 ½-ounce cartons and 6 1-ounce cartons of *Leuco-Derm Ointment Strong*, at Chicago, Ill. Examination showed that the products consisted of petrolatum, zinc oxide, and tar.

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements on the labels of the articles and in a circular enclosed in each carton and entitled "For Best Results and General Directions" were false and misleading. These statements represented and suggested that the articles were effective in the treatment of eczema, itch, and other skin conditions, psoriasis, chronic varicose ulcers, and weeping and itching skin conditions, whereas the articles were not effective in the treatment of such conditions.

DISPOSITION: September 8, 1948. Default decree of condemnation and destruction.

2664. Misbranding of Anbesol. U. S. v. 75 Cartons * * *. (F. D. C. No. 26025. Sample No. 11361–K.)

LIBEL FILED: November 12, 1948, Southern District of New York.

ALLEGED SHIPMENT: On or about September 20, 1948, by the Anbesol Co., from Newark, N. J.

PRODUCT: 75 cartons each containing 1 bottle of *Anbesol* and a circular entitled "You'll never know when you'll need Anbesol" at New York, N. Y. Examination showed that the product consisted essentially of alcohol 70%, benzocaine, a cresol, and glycerin with small proportions of carbolic acid and iodine.

NATURE OF CHARGE: Misbranding, Section 502 (a), the following statements in the labeling of the article were false and misleading since the article was not effective in the treatment of the conditions stated: (Carton) "Use for Teething Babies * * * sore gums * * * earache, sore throat"; (circular) "Kill infection * * * teething babies * * * toothache * * * mouth and lip sores * * * earache * * * sore gums * * * will prevent infection * * *."

DISPOSITION: December 3, 1948. Default decree of condemnation and destruction.

2665. Misbranding of Nycol. U. S. v. 46 Bottles, etc. (F. D. C. No. 24969. Sample No. 18897–K.)

LIBEL FILED: June 24, 1948, Northern District of Ohio.

ALLEGED SHIPMENT: On or about July 5 and October 27, 1947, and February 3 and March 11, 1948, by Nycol Products, Inc., from Ionia, Mich.

PRODUCT: 46 1-ounce bottles, 47 2-ounce bottles, 79 4-ounce bottles, and 105 8-ounce bottles of *Nycol* at Cleveland, Ohio. Examination showed that the product consisted essentially of water, nitric acid, and a small proportion of a camphoraceous material.

LABEL, IN PART: "Nycol Antiseptic Solution."

NATURE OF CHARGE: Misbranding, Section 502 (a), the following label statements were false and misleading since the article would not be effective in the treatment of the conditions represented: "Sore Throat (caused by colds or local infection) * * * use Nycol 3 or 4 times daily * * *," "* * * apply freely for * * * sore throat * * * eczema * * *," acne, impetigo, ringworm, * * * pityriasis, * * * barber's itch, seborrhea. Apply Nycol to afflicted area 4 or 5 times daily. Some skin ailments are caused by internal conditions. (Use Nycol to relieve effects and to prevent secondary infection)."

DISPOSITION: September 2, 1948. Default decree of condemnation and destruction.

2666. Misbranding of Ru-Mex-Ol Compound. U. S. v. 966 Dozen Bottles * * *. (F. D. C. No. 25147. Sample Nos. 27267–K, 45809–K, 45810–K.)

LIBEL FILED: August 3, 1948, Western District of Tennessee.

ALLEGED SHIPMENT: On or about April 28, May 26, and June 26 and 30, 1948, by the W. T. Rawleigh Co., from Freeport, Ill.

PRODUCT: 966 dozen bottles of *Ru-Mex-Ol Compound* at Memphis, Tenn. Examination showed that the product consisted of approximately 10 percent alcohol, 85 percent water, and 5 percent extractives from plant materials, and potassium iodide (0.4 grain per teaspoonful) and salicylic acid (0.3 grain per teaspoonful). A pharmacological test revealed that the article when taken as directed in the labeling, namely, "Adults 1 to 2 teaspoonfuls 3 times a day after meals," produced no laxative effect.

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements in the labeling of the article were false and misleading since they represented and suggested that the article when used as directed would produce alterative or laxative effects and that it would have a significant effect in stimulating the appetite, whereas the article when taken as directed would not be effective to produce alterative or laxative effects and would not have any significant effect in stimulating the appetite.

DISPOSITION: September 13, 1948. Default decree of condemnation and destruction.

2667. Misbranding of Ferguson's Zerret Applicator. U. S. v. 16 Devices * * *. (F. D. C. No. 25500. Sample No. 25863–K.)

LIBEL FILED: August 26, 1948, District of South Dakota.

ALLEGED SHIPMENT: By the firm, Ferguson's Zerret Applicator, from Chicago, Ill. The devices were shipped on or about July 8, 1948, and a number of circulars were shipped on or about August 6, 1948.

PRODUCT: 16 devices known as "*Ferguson's Zerret Applicator*" at Aberdeen, S. Dak., together with a number of circulars entitled "Directions for the use of the Zerret Applicator" and "Why Zerret Works." Examination showed that the device consisted of two plastic spheres joined together with a plastic band and containing a liquid. According to the labeling, when the device is held in the hands it will give off energy which exerts a curative effect. Tests showed that the device gives off no known type of energy.

NATURE OF CHARGE: Misbranding, Section 502(a), the following statements in the circular entitled "Why Zerret Works" and similar statements in the circular entitled "Directions for the use of the Zerret Applicator" were false and misleading since the statements represented and suggested that the device was effective in the treatment of disease, whereas it was not effective for such purposes: "Health Through the Hands * * * Zerret is produced by expanding the hydrogen Atom, which in turn produces positive Life Energy. When you hold the Zerret Applicator it works on your life current, expanding the Atoms of the same. As this takes place, it in turn expands all atoms of your being. Expansion of your Atoms produces what is commonly called Relaxation. As Relaxation is maintained from day to day, healing takes place in the most natural way. As this takes place there is a constant discharge of negative energy, which has been causing contraction of the Atoms, which in turn is the cause of all disease. You can readily see that through the use of Zerret we have the key to the cause and correction of disease. These are the facts about the Zerret Applicator. The Proof of the foregoing can only be ascertained by the use of the Applicator, To anyone who suffers from any known disease, you owe it to yourself to investigate this opportunity to become free from that suffering, and in this case, investigation means actually using the Zerret Applicator. If you do investigate, you will be given every cooperation to enjoy this wonderful discovery. We have proof of this from the hundreds of users, who are enjoying good health today. They are well because they did what we are asking you to do now * * * Act today for Health."

DISPOSITION: March 9, 1949. Ruby Dreier, Aberdeen, S. Dak., claimant, having filed an answer denying that the devices were misbranded, but later having consented to the entry of a decree, judgment of condemnation was entered and the devices were ordered destroyed.

DRUGS FOR VETERINARY USE*

2668. Misbranding of McClellan's Rex Liquid Special Rx 4 and McClellan's Poultry Virycide. U. S. v. 11 Bottles, etc. (F. D. C. No. 25999. Sample Nos. 29611–K, 29612–K.)

LIBEL FILED: November 10, 1948, District of Colorado.

ALLEGED SHIPMENT: On or about June 24, 1948, by C. U. McClellan Laboratories Corp. from Los Angeles, Calif.

PRODUCT: 11 quart bottles, 48 pint bottles, and 55 8-ounce bottles of *McClellan's Rex Liquid Special Rx 4*, and 10 gallon bottles, 18 quart bottles, and 17 pint bottles of *McClellan's Poultry Virycide* at Denver, Colo. Analyses of samples showed that the composition of the products was essentially as stated on their labels.

LABEL, IN PART: "McClellan's Rex Liquid Special Rx 4 For Poultry And Turkeys * * * Active Ingredient: diisobutylphenoxyethoxyethyl-dimethylbenzylammonium Chloride_____1.25% Inert Ingredients_____98.75% * * * These ingredients include Water, Isopropyl Alcohol (10%), Glauber Salts, Epsom Salts, Iron Sulfate, Salt, Lactic Acid, Potassium Iodide, Sodium Benzoate, Oil of Anise, Red Pepper * * *" and "McClellan's Poultry Virycide * * * Active Ingredient: Para Tertiary octyl phenoxy ethoxyethyl dimethyl benzyl ammonium chloride_____10% Inert Ingredients_____90% * * *."

*See also No. 2657.

NATURE OF CHARGE: *McClellan's Rex Liquid Special Rx 4.* Misbranding, Section 502 (a), certain statements on the label of the article were false and misleading since they represented and suggested that the article when used as directed was effective in the prevention and treatment of blackhead and coccidiosis of poultry and of pullorum and Newcastle diseases; that it was effective to stimulate digestive functioning, to increase appetite, and to build natural resistance in poultry to diseases; and that the Government had published reports of satisfactory tests showing that the article when used as directed was capable of killing the causative agents of coccidiosis, blackhead, and Newcastle diseases. The article was not effective for such purposes, and the Government had not published reports of such satisfactory tests.

McClellan's Poultry Virycide. Misbranding, Section 502 (a), the following statements on the label of the article were false and misleading since scientists in the U. S. Bureau of Animal Industry had not proved that the product when used as directed would kill the virus that causes Newcastle disease: "* * * Hatching Egg Disinfection: Hatching eggs may be dipped in a solution of McClellan's Poultry Virycide 2 ounces (4 tablespoonsfuls) to 3 gallons of water, left for 5 minutes, allowed to drain and then incubated in the usual way. Scientists of the U. S. Bureau of Animal Industry have proven that this treatment kills the virus that causes Newcastle Disease (Avian Pneumoencephalitis)."

DISPOSITION: December 23, 1948. Default decree of condemnation and destruction.

2669. Misbranding of Redd New Conditioner With Oil and Redd Laxative-Lubricant. U. S. v. 10 Bags, etc. (F. D. C. No. 25814. Sample Nos. 1308–K to 1310–K, incl.)

LIBEL FILED: On or about October 22, 1948, Northern District of Georgia.

ALLEGED SHIPMENT: On or about November 7, 1946, and October 23, 1947, by the Ivy Remedy Co., from New Market, Tenn.

PRODUCT: 10 50-pound bags and 1 25-pound bag of *Redd New Conditioner With Oil* and 6 25-pound bags of *Redd Laxative-Lubricant* at Gainesville, Ga. Analyses showed that the products consisted essentially of mineral matter, such as clay, iron oxide, mineral oil approximately 5 percent, and small proportions of plant material including alkaloid-bearing material, such as nux vomica.

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements on the labels of the articles were false and misleading. The statements represented and suggested that the articles were effective to keep chickens in condition; that they were effective in the treatment of all bowel disturbances of hens and turkeys; that they were effective to clear and clean gently but thoroughly the intestinal tract in hens and turkeys of mucus and bacterial pockets; that they were effective to keep hens and turkeys in condition and to prevent disease; that they were effective to heal sick hens and turkeys and to lubricate and keep the walls of the intestinal tract in a healthy condition; and that they were effective to save chicks from dying and disease. The articles were not effective for such purposes.

DISPOSITION: November 23, 1948. Default decree of condemnation and destruction.

2670. Misbranding of condensed buttermilk. U. S. v. 15 Barrels * * *. (F. D. C. No. 25988. Sample No. 25255–K.)

LIBEL FILED: November 1, 1948, Northern District of Iowa.

ALLEGED SHIPMENT: On or about July 26, 1948, by Frank Pilley & Sons, Inc., from Springfield, Mo. Accompanying the product were a number of leaflets and circulars.

PRODUCT: 15 500-pound barrels of *condensed buttermilk* at Waverly, Iowa. Analysis disclosed that the article contained less than 5 percent of lactic acid.

LABEL, IN PART: "Pilley's Farmland Feed Condensed Buttermilk 96½% Condensed Whey 2½% * * * Minimum Analysis * * * Lactic Acid 5.00%."

NATURE OF CHARGE: Misbranding, Section 502 (a), the following statements in the labeling were false and misleading since the product was not effective in the treatment of the diseases and conditions mentioned and was not effective for the purposes stated and implied: (Leaflet entitled "Instructions for Feeding") "for helping to maintain good digestion, and for providing the elements in the diet which promote big litters, easy farrowing, and sturdier, healthier, heavier pigs at farrowing time * * * Treatment for Necrotic Enteritis * * * Aid in Prevention of Disease * * * to keep the digestive organs functioning properly and thus able to throw off the impurities taken into the bird's system daily. Because of this ability Farmland Condensed Buttermilk Feed is recognized as an aid in the prevention of chicken and poultry diseases * * * Preventing Disease in Baby Chicks and Poults" and (circular entitled "For A Perfectly Balanced Poultry Ration") "For Proper Healthy Growth * * * Maintain Healthier Flocks * * * decreased mortality, sustained good health * * * but also safeguards against * * * leg weakness, coccidiosis and black head * * * for maintaining good digestion, which all poultry raisers agree is the basis for continuing good health in all poultry, both young and mature birds."

The product was alleged also to be adulterated and misbranded under the provisions of the law applicable to foods, as reported in notices of judgment on foods.

DISPOSITION: December 2, 1948. Default decree of condemnation and destruction.

INDEX TO NOTICES OF JUDGMENT D. D. N. J. NOS. 2651 TO 2670

PRODUCTS

[1] (2656) Injunction contested. Contains opinion of the court.

[2] (2657) Action for violation of injunction. Defendant found guilty of contempt.

SHIPPERS, MANUFACTURERS, AND DISTRIBUTORS

[1] (2656) Injunction contested. Contains opinion of the court.
[2] (2657) Action for violation of injunction. Defendant found guilty of contempt.
[3] (2652, 2654) Prosecution contested.

[2] (2657) Action for violation of injunction. Defendant found guilty of contempt.
[3] (2652, 2654) Prosecution contested.

U. S. GOVERNMENT PRINTING OFFICE: 1949